

## Safety Events from ICE3 Study Clinical Study Report

**Table 30: Adverse Event Summary – Primary Analysis Set**

	ICECURE (N= 194)			Kaplan-Meier**			
	Events†	Subjs‡	%°	Year 2	Year 5	Year 2 1-sided 95% CI UB	Year 5 1-sided 95% CI UB
<b>Adverse Events</b>							
All	517	140	72.2%	61.0%	73.1%	66.8%	78.3%
Procedure Related	180	93	47.9%	46.9%	48.2%	53.0%	54.2%
<b>Serious Adverse Events</b>							
All	127	59	30.4%	9.9%	31.5%	14.2%	37.7%
Procedure Related	4	3	1.5%	0.0%	1.9%	0.0%	4.9%
<b>Adverse Events by Severity</b>							
Mild	333	108	55.7%	54.7%	56.9%	60.7%	63.0%
Moderate	92	52	26.8%	18.2%	28.1%	23.4%	34.2%
Severe	92	47	24.2%	9.9%	25.7%	14.1%	31.6%
<b>Serious Adverse Events by Severity</b>							
Mild	5	3	1.5%	0.6%	1.8%	2.9%	4.6%
Moderate	35	25	12.9%	3.7%	14.0%	6.8%	19.2%
Severe	87	42	21.6%	7.3%	23.4%	11.1%	29.2%
<b>Deaths</b>							
All	21	21	10.8%	3.6%	10.3%	6.6%	14.5%
† Total number of events without regard to length of follow-up. ‡ Number of subjects experiencing event without regard to length of follow-up. ° Percentage of subjects experiencing specific event without regard to length of follow-up. ** Kaplan-Meier Estimates at day 365, 730, 1095, 1460, and 1825 with 1-sided 95% CI upper bound (UB). Procedure relationship: Remotely, Possible, Probable, Unknown. Source: Table 5_1 AE Summary_FAS v2.sas; Analyzed: 09JUN2024							

Table 31: All Adverse Events– Primary Analysis Set (N=194)

	ICECURE (N= 194)			Kaplan-Meier**			
	Events†	Subjs‡	%°	Year 2	Year 5	Year 2 1-sided 95% CI UB	Year 5 1-sided 95% CI UB
<b>All Events</b>	<b>517</b>	<b>140</b>	<b>72.2%</b>	<b>61.0%</b>	<b>73.1%</b>	<b>66.8%</b>	<b>78.3%</b>
<b>Blood and lymphatic system disorders</b>	<b>7</b>	<b>6</b>	<b>3.1%</b>	<b>2.1%</b>	<b>3.6%</b>	<b>4.7%</b>	<b>6.9%</b>
Anemia	1	1	0.5%	0.0%	0.8%	0.0%	3.9%
Febrile Neutropenia	2	2	1.0%	0.5%	1.2%	2.7%	3.9%
Leukocytosis	2	1	0.5%	0.5%	0.5%	2.7%	2.7%
Lymph node pain	2	2	1.0%	1.1%	1.1%	3.4%	3.4%
<b>Cardiac disorders</b>	<b>23</b>	<b>17</b>	<b>8.8%</b>	<b>3.3%</b>	<b>10.0%</b>	<b>6.3%</b>	<b>14.5%</b>
Acute coronary syndrome	1	1	0.5%	0.0%	0.6%	0.0%	3.3%
Aortic valve disease	1	1	0.5%	0.0%	0.6%	0.0%	3.0%
Atrial fibrillation	4	3	1.5%	0.5%	1.1%	2.8%	3.6%
Atrial flutter	1	1	0.5%	0.0%	0.6%	0.0%	3.3%
Atrioventricular Block Complete	1	1	0.5%	0.0%	0.6%	0.0%	3.1%
Cardiac arrest	2	2	1.0%	0.0%	1.2%	0.0%	3.9%
Chest pain - cardiac	2	1	0.5%	0.0%	0.7%	0.0%	3.5%
Heart failure	5	4	2.1%	0.5%	2.5%	2.7%	5.5%
Myocardial infarction	2	2	1.0%	0.5%	1.2%	2.8%	3.8%
Palpitations	3	3	1.5%	1.6%	1.6%	4.2%	4.2%
Sick sinus syndrome	1	1	0.5%	0.0%	0.6%	0.0%	3.3%
<b>Ear and labyrinth disorders</b>	<b>5</b>	<b>3</b>	<b>1.5%</b>	<b>1.6%</b>	<b>1.6%</b>	<b>4.2%</b>	<b>4.2%</b>
Ear Pain	1	1	0.5%	0.6%	0.6%	2.8%	2.8%
Hearing impaired	2	2	1.0%	1.1%	1.1%	3.5%	3.5%
Tinnitus	1	1	0.5%	0.5%	0.5%	2.8%	2.8%
Vestibular Disorder	1	1	0.5%	0.5%	0.5%	2.7%	2.7%
<b>Eye disorders</b>	<b>2</b>	<b>2</b>	<b>1.0%</b>	<b>1.1%</b>	<b>1.1%</b>	<b>3.4%</b>	<b>3.4%</b>
Cataract	1	1	0.5%	0.5%	0.5%	2.8%	2.8%
Macular degeneration	1	1	0.5%	0.5%	0.5%	2.7%	2.7%
<b>Gastrointestinal disorders</b>	<b>23</b>	<b>18</b>	<b>9.3%</b>	<b>5.2%</b>	<b>10.6%</b>	<b>8.6%</b>	<b>15.4%</b>
Abdominal Distension	1	1	0.5%	0.5%	0.5%	2.7%	2.7%
Abdominal pain	4	4	2.1%	1.0%	2.3%	3.3%	5.2%
Colitis	1	1	0.5%	0.5%	0.5%	2.7%	2.7%
Constipation	7	6	3.1%	2.6%	3.3%	5.4%	6.4%
Diarrhea	3	3	1.5%	1.1%	1.6%	3.3%	4.2%
Duodenal hemorrhage	1	1	0.5%	0.0%	0.6%	0.0%	3.3%
Dyspepsia	1	1	0.5%	0.5%	0.5%	2.8%	2.8%
Dysphagia	1	1	0.5%	0.0%	0.7%	0.0%	3.8%
Obstruction gastric	2	1	0.5%	0.0%	0.6%	0.0%	3.3%
Sigmoid diverticulitis	1	1	0.5%	0.0%	0.8%	0.0%	4.0%
Small intestinal obstruction	1	1	0.5%	0.0%	0.7%	0.0%	3.5%

	ICECURE (N= 194)			Kaplan-Meier**			
	Events†	Subjs‡	%°	Year 2	Year 5	Year 2 1-sided 95% CI UB	Year 5 1-sided 95% CI UB
<b>General disorders and administration site conditions</b>	<b>125</b>	<b>81</b>	<b>41.8%</b>	<b>40.5%</b>	<b>42.5%</b>	<b>46.6%</b>	<b>48.6%</b>
COVID	3	2	1.0%	0.0%	1.4%	0.0%	4.3%
Chills	1	1	0.5%	0.5%	0.5%	2.7%	2.7%
Death NOS	3	3	1.5%	0.0%	1.9%	0.0%	4.8%
Edema limbs	2	2	1.0%	0.6%	1.2%	2.8%	4.0%
Edema of limbs	1	1	0.5%	0.5%	0.5%	2.7%	2.7%
Fatigue	15	14	7.2%	6.8%	7.6%	10.5%	11.6%
Heat sensation	2	1	0.5%	0.5%	0.5%	2.6%	2.6%
Infusion site extravasation	1	1	0.5%	0.5%	0.5%	2.6%	2.6%
Injection site reaction	11	10	5.2%	5.2%	5.2%	8.6%	8.6%
Irritability	1	1	0.5%	0.5%	0.5%	2.7%	2.7%
Localized edema	38	37	19.1%	19.1%	19.1%	24.3%	24.3%
Malaise	1	1	0.5%	0.5%	0.5%	2.7%	2.7%
Multi-organ failure	1	1	0.5%	0.6%	0.6%	2.8%	2.8%
Non-cardiac chest pain	2	2	1.0%	1.0%	1.0%	3.3%	3.3%
Pain	43	39	20.1%	19.7%	20.3%	24.9%	25.7%
<b>Infections and infestations</b>	<b>31</b>	<b>21</b>	<b>10.8%</b>	<b>7.4%</b>	<b>11.2%</b>	<b>11.3%</b>	<b>15.9%</b>
Endocarditis infective	1	1	0.5%	0.0%	0.6%	0.0%	3.0%
Lung infection	6	6	3.1%	0.5%	2.6%	2.7%	6.0%
Papulopustular Rash	1	1	0.5%	0.5%	0.5%	2.7%	2.7%
Rash Pustular	1	1	0.5%	0.5%	0.5%	2.7%	2.7%
Sepsis	3	3	1.5%	0.6%	2.0%	2.8%	5.0%
Skin infection	15	9	4.6%	4.8%	4.8%	8.2%	8.2%
Upper respiratory infection	1	1	0.5%	0.0%	0.8%	0.0%	3.9%
Urinary tract infection	3	3	1.5%	1.0%	1.6%	3.3%	4.1%
<b>Injury, poisoning and procedural complications</b>	<b>77</b>	<b>67</b>	<b>34.5%</b>	<b>32.0%</b>	<b>34.7%</b>	<b>37.9%</b>	<b>40.8%</b>
Bruising	57	57	29.4%	29.4%	29.4%	35.1%	35.1%
Burn	4	4	2.1%	2.1%	2.1%	4.6%	4.6%
Dermatitis radiation	3	3	1.5%	1.6%	1.6%	4.0%	4.0%
Fall	8	8	4.1%	2.1%	4.1%	4.7%	7.7%
Fracture	3	3	1.5%	1.6%	1.6%	4.1%	4.1%
Hip fracture	1	1	0.5%	0.0%	0.7%	0.0%	3.4%
postoperative hemorrhage	1	1	0.5%	0.5%	0.5%	2.6%	2.6%
<b>Investigations</b>	<b>4</b>	<b>3</b>	<b>1.5%</b>	<b>1.0%</b>	<b>1.7%</b>	<b>3.3%</b>	<b>4.3%</b>
Cholesterol high	1	1	0.5%	0.0%	0.6%	0.0%	3.3%
Weight loss	3	2	1.0%	1.0%	1.0%	3.3%	3.3%
<b>Metabolism and nutrition disorders</b>	<b>5</b>	<b>5</b>	<b>2.6%</b>	<b>0.5%</b>	<b>2.4%</b>	<b>2.7%</b>	<b>5.4%</b>
Anorexia	1	1	0.5%	0.0%	0.6%	0.0%	3.0%
Hypercalcemia	1	1	0.5%	0.5%	0.5%	2.7%	2.7%
Hypertriglyceridemia	1	1	0.5%	0.0%	0.6%	0.0%	3.3%
Hypokalemia	1	1	0.5%	0.0%	0.0%	0.0%	0.0%
Malnutrition	1	1	0.5%	0.0%	0.7%	0.0%	3.4%

	ICECURE (N= 194)			Kaplan-Meier**			
	Events†	Subjs‡	%°	Year 2	Year 5	Year 2 1-sided 95% CI UB	Year 5 1-sided 95% CI UB
<b>Musculoskeletal and connective tissue disorders</b>	<b>45</b>	<b>28</b>	<b>14.4%</b>	<b>12.7%</b>	<b>15.2%</b>	<b>17.3%</b>	<b>20.1%</b>
Arthralgia	16	15	7.7%	7.0%	8.1%	10.8%	12.2%
Arthritis	3	3	1.5%	1.1%	1.8%	3.5%	4.6%
Back pain	7	6	3.1%	2.6%	3.2%	5.4%	6.3%
Flank Pain	1	1	0.5%	0.0%	0.6%	0.0%	2.9%
Generalized muscle weakness	1	1	0.5%	0.6%	0.6%	2.9%	2.9%
Myalgia	4	3	1.5%	1.1%	1.7%	3.4%	4.3%
Neck pain	2	2	1.0%	0.5%	1.1%	2.6%	3.4%
Osteoporosis	1	1	0.5%	0.0%	0.7%	0.0%	3.8%
Pain in extremity	7	6	3.1%	3.2%	3.2%	6.1%	6.1%
Rhabdomyolysis	1	1	0.5%	0.0%	0.6%	0.0%	3.3%
Superficial soft tissue fibrosis	2	1	0.5%	0.5%	0.5%	2.7%	2.7%
<b>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</b>	<b>25</b>	<b>24</b>	<b>12.4%</b>	<b>3.2%</b>	<b>13.7%</b>	<b>6.2%</b>	<b>18.9%</b>
Acute Myeloid Leukemia	1	1	0.5%	0.0%	0.6%	0.0%	3.3%
Benign Neoplasm	1	1	0.5%	0.0%	0.7%	0.0%	3.6%
DCIS Left Breast	1	1	0.5%	0.0%	0.6%	0.0%	3.0%
Diffuse Metastatic disease to the bones	1	1	0.5%	0.0%	0.7%	0.0%	3.4%
Endometrial Cancer	2	2	1.0%	0.0%	1.2%	0.0%	3.8%
Endometrial Cyst	1	1	0.5%	0.6%	0.6%	2.8%	2.8%
Epidermal Inclusion Cyst	1	1	0.5%	0.5%	0.5%	2.7%	2.7%
Hepatocellular carcinoma	1	1	0.5%	0.0%	0.7%	0.0%	3.5%
Kidney cancer	1	1	0.5%	0.0%	0.8%	0.0%	4.3%
Local recurrence	7	7	3.6%	0.0%	4.7%	0.0%	8.6%
Lung Adenocarcinoma	1	1	0.5%	0.5%	0.5%	2.8%	2.8%
Meningioma	1	1	0.5%	0.5%	0.5%	2.7%	2.7%
Metastatic breast cancer	1	1	0.5%	0.0%	0.7%	0.0%	3.6%
Mole	1	1	0.5%	0.6%	0.6%	2.8%	2.8%
Non-small cell lung cancer	1	1	0.5%	0.5%	0.5%	2.8%	2.8%
Second primary BC	3	3	1.5%	0.0%	0.7%	0.0%	3.7%
<b>Nervous system disorders</b>	<b>27</b>	<b>22</b>	<b>11.3%</b>	<b>7.4%</b>	<b>11.8%</b>	<b>11.2%</b>	<b>16.5%</b>
Altered mental status	1	1	0.5%	0.0%	0.7%	0.0%	3.5%
Dizziness	4	3	1.5%	1.1%	1.1%	3.4%	3.4%
Encephalopathy	1	1	0.5%	0.5%	0.5%	2.7%	2.7%
Headache	3	3	1.5%	1.6%	1.6%	4.0%	4.0%
Intracranial hemorrhage	1	1	0.5%	0.5%	0.5%	2.7%	2.7%
Memory impairment	6	6	3.1%	1.6%	3.5%	4.0%	6.7%
Paresthesia	2	2	1.0%	1.0%	1.0%	3.3%	3.3%
Peripheral sensory neuropathy	1	1	0.5%	0.5%	0.5%	2.7%	2.7%
Presyncope	1	1	0.5%	0.0%	0.6%	0.0%	3.0%
Seizure	1	1	0.5%	0.5%	0.5%	2.8%	2.8%
Spasticity	1	1	0.5%	0.6%	0.6%	2.9%	2.9%
Stroke	2	2	1.0%	0.5%	1.2%	2.7%	3.9%

	ICECURE (N= 194)			Kaplan-Meier**			
	Events†	Subjs‡	%°	Year 2	Year 5	Year 2 1-sided 95% CI UB	Year 5 1-sided 95% CI UB
Syncope	1	1	0.5%	0.0%	0.7%	0.0%	3.5%
Thoracic stenosis	1	1	0.5%	0.6%	0.6%	2.9%	2.9%
Transient ischemic attacks	1	1	0.5%	0.6%	0.6%	2.8%	2.8%
<b>Psychiatric disorders</b>	<b>14</b>	<b>12</b>	<b>6.2%</b>	<b>6.4%</b>	<b>6.4%</b>	<b>10.1%</b>	<b>10.1%</b>
Anxiety	6	6	3.1%	3.2%	3.2%	6.1%	6.1%
Depression	3	3	1.5%	1.6%	1.6%	4.1%	4.1%
Insomnia	4	4	2.1%	2.1%	2.1%	4.8%	4.8%
Psychiatric disorders - Other Mild	1	1	0.5%	0.5%	0.5%	2.6%	2.6%
<b>Renal and urinary disorders</b>	<b>11</b>	<b>9</b>	<b>4.6%</b>	<b>3.2%</b>	<b>5.2%</b>	<b>6.2%</b>	<b>8.9%</b>
Acute kidney injury	4	4	2.1%	1.1%	2.4%	3.4%	5.5%
Hematuria	1	1	0.5%	0.5%	0.5%	2.7%	2.7%
Urinary frequency	2	2	1.0%	1.1%	1.1%	3.4%	3.4%
Urinary incontinence	3	2	1.0%	1.1%	1.1%	3.4%	3.4%
urinary tract pain	1	1	0.5%	0.0%	0.6%	0.0%	3.0%
<b>Reproductive system and breast disorders</b>	<b>6</b>	<b>4</b>	<b>2.1%</b>	<b>1.6%</b>	<b>2.3%</b>	<b>4.0%</b>	<b>5.3%</b>
Breast twitches	1	1	0.5%	0.5%	0.5%	2.6%	2.6%
Dimpling	1	1	0.5%	0.5%	0.5%	2.7%	2.7%
Dyspareunia	1	1	0.5%	0.5%	0.5%	2.8%	2.8%
Tethering	1	1	0.5%	0.5%	0.5%	2.7%	2.7%
Vaginal dryness	2	2	1.0%	0.5%	1.3%	2.8%	4.1%
<b>Respiratory, thoracic and mediastinal disorders</b>	<b>37</b>	<b>22</b>	<b>11.3%</b>	<b>6.9%</b>	<b>11.1%</b>	<b>10.6%</b>	<b>15.7%</b>
Aspiration	2	1	0.5%	0.5%	0.5%	2.8%	2.8%
Atelectasis	1	1	0.5%	0.0%	0.8%	0.0%	3.9%
COPD	2	2	1.0%	0.5%	0.5%	2.8%	2.8%
Cough	6	5	2.6%	2.7%	2.7%	5.5%	5.5%
Dyspnea	11	8	4.1%	2.1%	4.6%	4.7%	8.2%
Emphysema	1	1	0.5%	0.5%	0.5%	2.8%	2.8%
Hypoxia	2	1	0.5%	0.5%	0.5%	2.8%	2.8%
Nasal congestion	1	1	0.5%	0.5%	0.5%	2.8%	2.8%
Pleural effusion	6	5	2.6%	0.6%	1.8%	2.8%	4.6%
Pulmonary edema	1	1	0.5%	0.0%	0.6%	0.0%	3.1%
Respiratory failure	4	4	2.1%	1.6%	1.6%	4.0%	4.0%
<b>Skin and subcutaneous tissue disorders</b>	<b>21</b>	<b>17</b>	<b>8.8%</b>	<b>8.9%</b>	<b>8.9%</b>	<b>12.9%</b>	<b>12.9%</b>
Alopecia	1	1	0.5%	0.5%	0.5%	2.7%	2.7%
Body odor	1	1	0.5%	0.5%	0.5%	2.6%	2.6%
Drainage	1	1	0.5%	0.5%	0.5%	2.6%	2.6%
Dry skin	1	1	0.5%	0.5%	0.5%	2.7%	2.7%
Erythema multiforme	7	6	3.1%	3.1%	3.1%	6.1%	6.1%
Hirsutism	1	1	0.5%	0.5%	0.5%	2.7%	2.7%
Pruritus	6	6	3.1%	2.6%	3.4%	5.3%	6.6%
Rash acneiform	1	1	0.5%	0.5%	0.5%	2.6%	2.6%
Skin hyperpigmentation	1	1	0.5%	0.5%	0.5%	2.7%	2.7%

	ICECURE (N= 194)			Kaplan-Meier**			
	Events†	Subjs‡	%°	Year 2	Year 5	Year 2 1-sided 95% CI UB	Year 5 1-sided 95% CI UB
Skin rash	1	1	0.5%	0.5%	0.5%	2.6%	2.6%
<b>Surgical and medical procedures</b>	<b>2</b>	<b>2</b>	<b>1.0%</b>	<b>0.5%</b>	<b>1.3%</b>	<b>2.6%</b>	<b>4.1%</b>
Herniorrhaphy /Hernioplasty	1	1	0.5%	0.0%	0.8%	0.0%	3.9%
Yellow discharge	1	1	0.5%	0.5%	0.5%	2.6%	2.6%
<b>Vascular disorders</b>	<b>27</b>	<b>25</b>	<b>12.9%</b>	<b>11.0%</b>	<b>13.4%</b>	<b>15.3%</b>	<b>18.1%</b>
Bilateral Carotid Stenosis	1	1	0.5%	0.0%	0.6%	0.0%	3.2%
Flushing	1	1	0.5%	0.5%	0.5%	2.6%	2.6%
Hematoma	9	9	4.6%	4.6%	4.6%	7.9%	7.9%
Hot flashes	9	9	4.6%	3.7%	4.9%	6.7%	8.3%
Hypertension	4	4	2.1%	1.1%	2.3%	3.4%	5.1%
Thromboembolic event	3	3	1.5%	1.6%	1.6%	4.1%	4.1%

† Total number of events without regard to length of follow-up.  
‡ Number of subjects experiencing event without regard to length of follow-up.  
° Percentage of subjects experiencing specific event without regard to length of follow-up.  
\*\* Kaplan-Meier Estimates at day 365, 730, 1095, 1460, and 1825 with 1-sided 95% CI upper bond (UB).  
Procedure relationship: Remotely, Possible, Probable, Unknown.  
Adverse events with missing date are analyzed as relative day 1.  
Source: Tables Safety\_FAS.sas; Analyzed: 09JUN2024

**Table 32: All Adverse Events by High Term – Primary Analysis Set (N=194)**

	ICECURE (N= 194)			Kaplan-Meier**			
	Events†	Subjs‡	%°	Year 2	Year 5	Year 2 1-sided 95% CI UB	Year 5 1-sided 95% CI UB
<b>All Events</b>	<b>517</b>	<b>140</b>	<b>72.2%</b>	<b>61.0%</b>	<b>73.1%</b>	<b>66.8%</b>	<b>78.3%</b>
<b>Blood and lymphatic system disorders</b>	<b>7</b>	<b>6</b>	<b>3.1%</b>	<b>2.1%</b>	<b>3.6%</b>	<b>4.7%</b>	<b>6.9%</b>
<b>Cardiac disorders</b>	<b>23</b>	<b>17</b>	<b>8.8%</b>	<b>3.3%</b>	<b>10.0%</b>	<b>6.3%</b>	<b>14.5%</b>
<b>Ear and labyrinth disorders</b>	<b>5</b>	<b>3</b>	<b>1.5%</b>	<b>1.6%</b>	<b>1.6%</b>	<b>4.2%</b>	<b>4.2%</b>
<b>Eye disorders</b>	<b>2</b>	<b>2</b>	<b>1.0%</b>	<b>1.1%</b>	<b>1.1%</b>	<b>3.4%</b>	<b>3.4%</b>
<b>Gastrointestinal disorders</b>	<b>23</b>	<b>18</b>	<b>9.3%</b>	<b>5.2%</b>	<b>10.6%</b>	<b>8.6%</b>	<b>15.4%</b>
<b>General disorders and administration site co</b>	<b>125</b>	<b>81</b>	<b>41.8%</b>	<b>40.5%</b>	<b>42.5%</b>	<b>46.6%</b>	<b>48.6%</b>
<b>Infections and infestations</b>	<b>31</b>	<b>21</b>	<b>10.8%</b>	<b>7.4%</b>	<b>11.2%</b>	<b>11.3%</b>	<b>15.9%</b>
<b>Injury, poisoning and procedural complication</b>	<b>77</b>	<b>67</b>	<b>34.5%</b>	<b>32.0%</b>	<b>34.7%</b>	<b>37.9%</b>	<b>40.8%</b>
<b>Investigations</b>	<b>4</b>	<b>3</b>	<b>1.5%</b>	<b>1.0%</b>	<b>1.7%</b>	<b>3.3%</b>	<b>4.3%</b>
<b>Metabolism and nutrition disorders</b>	<b>5</b>	<b>5</b>	<b>2.6%</b>	<b>0.5%</b>	<b>2.4%</b>	<b>2.7%</b>	<b>5.4%</b>
<b>Musculoskeletal and connective tissue disor</b>	<b>45</b>	<b>28</b>	<b>14.4%</b>	<b>12.7%</b>	<b>15.2%</b>	<b>17.3%</b>	<b>20.1%</b>
<b>Neoplasms benign, malignant and unspecifie</b>	<b>25</b>	<b>24</b>	<b>12.4%</b>	<b>3.2%</b>	<b>13.7%</b>	<b>6.2%</b>	<b>18.9%</b>
<b>Nervous system disorders</b>	<b>27</b>	<b>22</b>	<b>11.3%</b>	<b>7.4%</b>	<b>11.8%</b>	<b>11.2%</b>	<b>16.5%</b>
<b>Psychiatric disorders</b>	<b>14</b>	<b>12</b>	<b>6.2%</b>	<b>6.4%</b>	<b>6.4%</b>	<b>10.1%</b>	<b>10.1%</b>
<b>Renal and urinary disorders</b>	<b>11</b>	<b>9</b>	<b>4.6%</b>	<b>3.2%</b>	<b>5.2%</b>	<b>6.2%</b>	<b>8.9%</b>
<b>Reproductive system and breast disorders</b>	<b>6</b>	<b>4</b>	<b>2.1%</b>	<b>1.6%</b>	<b>2.3%</b>	<b>4.0%</b>	<b>5.3%</b>
<b>Respiratory, thoracic and mediastinal disorde</b>	<b>37</b>	<b>22</b>	<b>11.3%</b>	<b>6.9%</b>	<b>11.1%</b>	<b>10.6%</b>	<b>15.7%</b>
<b>Skin and subcutaneous tissue disorders</b>	<b>21</b>	<b>17</b>	<b>8.8%</b>	<b>8.9%</b>	<b>8.9%</b>	<b>12.9%</b>	<b>12.9%</b>
<b>Surgical and medical procedures</b>	<b>2</b>	<b>2</b>	<b>1.0%</b>	<b>0.5%</b>	<b>1.3%</b>	<b>2.6%</b>	<b>4.1%</b>
<b>Vascular disorders</b>	<b>27</b>	<b>25</b>	<b>12.9%</b>	<b>11.0%</b>	<b>13.4%</b>	<b>15.3%</b>	<b>18.1%</b>

† Total number of events without regard to length of follow-up.  
‡ Number of subjects experiencing event without regard to length of follow-up.  
° Percentage of subjects experiencing specific event without regard to length of follow-up.  
\*\* Kaplan-Meier Estimates at day 365, 730, 1095, 1460, and 1825 with 1-sided 95% CI upper bond (UB).  
Procedure relationship: Remotely, Possible, Probable, Unknown.  
Adverse events with missing date are analyzed as relative day 1.  
Source: Tables Safety\_FAS.sas; Analyzed: 09JUN2024

**Table 33: All Adverse Events by Timecourse – Primary Analysis Group**

	0	1-30	31-60	61-180	181-365	366-730	731-1095	1096-1460	1461-1825	>1825	Total
<b>All Events</b>	<b>66</b>	<b>114</b>	<b>8</b>	<b>44</b>	<b>90</b>	<b>68</b>	<b>42</b>	<b>32</b>	<b>39</b>	<b>14</b>	<b>517</b>
<b>Blood and lymphatic system disorders</b>	<b>0</b>	<b>0</b>	<b>2</b>	<b>1</b>	<b>1</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>2</b>	<b>0</b>	<b>7</b>
Anemia	0	0	0	0	0	0	0	0	1	0	1
Febrile Neutropenia	0	0	0	1	0	0	0	0	1	0	2
Leukocytosis	0	0	2	0	0	0	0	0	0	0	2
Lymph node pain	0	0	0	0	1	1	0	0	0	0	2
<b>Cardiac disorders</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>5</b>	<b>5</b>	<b>8</b>	<b>2</b>	<b>2</b>	<b>23</b>
Acute coronary syndrome	0	0	0	0	0	0	0	1	0	0	1
Aortic valve disease	0	0	0	0	0	0	1	0	0	0	1
Atrial fibrillation	0	0	0	0	0	1	1	0	1	1	4
Atrial flutter	0	0	0	0	0	0	0	1	0	0	1
Atrioventricular Block Complete	0	0	0	0	0	0	1	0	0	0	1
Cardiac arrest	0	0	0	0	0	0	1	1	0	0	2

	0	1-30	31-60	61-180	181-365	366-730	731-1095	1096-1460	1461-1825	>1825	Total
Chest pain - cardiac	0	0	0	0	0	0	0	1	0	1	2
Heart failure	0	0	0	0	1	0	1	2	1	0	5
Myocardial infarction	0	0	0	0	0	1	0	1	0	0	2
Palpitations	0	0	0	0	0	3	0	0	0	0	3
Sick sinus syndrome	0	0	0	0	0	0	0	1	0	0	1
<b>Ear and labyrinth disorders</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>4</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>5</b>
Ear Pain	0	0	0	0	0	1	0	0	0	0	1
Hearing impaired	0	0	0	0	0	2	0	0	0	0	2
Tinnitus	0	0	0	0	0	1	0	0	0	0	1
Vestibular Disorder	0	0	0	1	0	0	0	0	0	0	1
<b>Eye disorders</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>2</b>
Cataract	0	0	0	0	0	1	0	0	0	0	1
Macular degeneration	0	0	0	1	0	0	0	0	0	0	1
<b>Gastrointestinal disorders</b>	<b>0</b>	<b>0</b>	<b>2</b>	<b>3</b>	<b>6</b>	<b>2</b>	<b>2</b>	<b>4</b>	<b>4</b>	<b>0</b>	<b>23</b>
Abdominal Distension	0	0	0	1	0	0	0	0	0	0	1
Abdominal pain	0	0	0	0	2	0	1	1	0	0	4
Colitis	0	0	0	0	1	0	0	0	0	0	1
Constipation	0	0	2	2	1	1	0	0	1	0	7
Diarrhea	0	0	0	0	2	0	1	0	0	0	3
Duodenal hemorrhage	0	0	0	0	0	0	0	1	0	0	1
Dyspepsia	0	0	0	0	0	1	0	0	0	0	1
Dysphagia	0	0	0	0	0	0	0	0	1	0	1
Obstruction gastric	0	0	0	0	0	0	0	2	0	0	2
Sigmoid diverticulitis	0	0	0	0	0	0	0	0	1	0	1
Small intestinal obstruction	0	0	0	0	0	0	0	0	1	0	1
<b>General disorders and administration site conditions</b>	<b>34</b>	<b>50</b>	<b>1</b>	<b>5</b>	<b>18</b>	<b>7</b>	<b>3</b>	<b>3</b>	<b>4</b>	<b>0</b>	<b>125</b>
COVID	0	0	0	0	0	0	0	1	2	0	3
Chills	0	0	0	0	1	0	0	0	0	0	1
Death NOS	0	0	0	0	0	0	2	1	0	0	3
Edema limbs	0	0	0	0	0	1	0	0	1	0	2
Edema of limbs	0	0	0	1	0	0	0	0	0	0	1
Fatigue	1	2	0	2	7	1	1	0	1	0	15
Heat sensation	0	1	0	0	0	1	0	0	0	0	2
Infusion site extravasation	0	1	0	0	0	0	0	0	0	0	1
Injection site reaction	3	6	0	0	0	2	0	0	0	0	11
Irritability	0	0	0	0	1	0	0	0	0	0	1
Localized edema	11	24	0	1	2	0	0	0	0	0	38
Malaise	0	0	0	0	1	0	0	0	0	0	1
Multi-organ failure	0	0	0	0	0	1	0	0	0	0	1
Non-cardiac chest pain	1	0	0	0	1	0	0	0	0	0	2
Pain	18	16	1	1	5	1	0	1	0	0	43
<b>Infections and infestations</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>7</b>	<b>7</b>	<b>5</b>	<b>3</b>	<b>2</b>	<b>4</b>	<b>2</b>	<b>31</b>
Endocarditis infective	0	0	0	0	0	0	1	0	0	0	1
Lung infection	0	0	1	0	0	0	0	2	1	2	6
Papulopustular Rash	0	0	0	1	0	0	0	0	0	0	1
Rash Pustular	0	0	0	0	1	0	0	0	0	0	1
Sepsis	0	0	0	0	0	1	0	0	2	0	3
Skin infection	0	0	0	5	5	4	1	0	0	0	15
Upper respiratory infection	0	0	0	0	0	0	0	0	1	0	1
Urinary tract infection	0	0	0	1	1	0	1	0	0	0	3

	0	1-30	31-60	61-180	181-365	366-730	731-1095	1096-1460	1461-1825	>1825	Total
<b>Injury, poisoning and procedural complications</b>	<b>18</b>	<b>45</b>	<b>1</b>	<b>3</b>	<b>4</b>	<b>1</b>	<b>1</b>	<b>1</b>	<b>2</b>	<b>1</b>	<b>77</b>
Bruising	16	41	0	0	0	0	0	0	0	0	57
Burn	1	3	0	0	0	0	0	0	0	0	4
Dermatitis radiation	0	1	1	0	1	0	0	0	0	0	3
Fall	0	0	0	2	2	0	1	0	2	1	8
Fracture	0	0	0	1	1	1	0	0	0	0	3
Hip fracture	0	0	0	0	0	0	0	1	0	0	1
postoperative hemorrhage	1	0	0	0	0	0	0	0	0	0	1
<b>Investigations</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>1</b>	<b>0</b>	<b>1</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>4</b>
Cholesterol high	0	0	0	0	0	0	0	1	0	0	1
Weight loss	0	0	0	1	1	0	1	0	0	0	3
<b>Metabolism and nutrition disorders</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>1</b>	<b>2</b>	<b>0</b>	<b>1</b>	<b>5</b>
Anorexia	0	0	0	0	0	0	1	0	0	0	1
Hypercalcemia	0	0	0	0	1	0	0	0	0	0	1
Hypertriglyceridemia	0	0	0	0	0	0	0	1	0	0	1
Hypokalemia	0	0	0	0	0	0	0	0	0	1	1
Malnutrition	0	0	0	0	0	0	0	1	0	0	1
<b>Musculoskeletal and connective tissue disorders</b>	<b>1</b>	<b>2</b>	<b>0</b>	<b>5</b>	<b>14</b>	<b>12</b>	<b>7</b>	<b>2</b>	<b>2</b>	<b>0</b>	<b>45</b>
Arthralgia	0	0	0	0	10	4	2	0	0	0	16
Arthritis	0	0	0	0	1	1	0	0	1	0	3
Back pain	0	1	0	1	1	2	2	0	0	0	7
Flank Pain	0	0	0	0	0	0	1	0	0	0	1
Generalized muscle weakness	0	0	0	0	0	1	0	0	0	0	1
Myalgia	0	0	0	1	0	2	1	0	0	0	4
Neck pain	0	1	0	0	0	0	1	0	0	0	2
Osteoporosis	0	0	0	0	0	0	0	0	1	0	1
Pain in extremity	1	0	0	2	2	1	0	1	0	0	7
Rhabdomyolysis	0	0	0	0	0	0	0	1	0	0	1
Superficial soft tissue fibrosis	0	0	0	1	0	1	0	0	0	0	2
<b>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>5</b>	<b>4</b>	<b>8</b>	<b>2</b>	<b>25</b>
Acute Myeloid Leukemia	0	0	0	0	0	0	0	1	0	0	1
Benign Neoplasm	0	0	0	0	0	0	0	0	1	0	1
DCIS Left Breast	0	0	0	0	0	0	1	0	0	0	1
Diffuse Metastatic disease to the bones	0	0	0	0	0	0	0	1	0	0	1
Endometrial Cancer	0	0	0	0	0	0	2	0	0	0	2
Endometrial Cyst	0	0	0	0	0	1	0	0	0	0	1
Epidermal Inclusion Cyst	0	0	0	0	1	0	0	0	0	0	1
Hepatocellular carcinoma	0	0	0	0	0	0	0	1	0	0	1
Kidney cancer	0	0	0	0	0	0	0	0	1	0	1
Local recurrence	0	0	0	0	0	0	2	1	4	0	7
Lung Adenocarcinoma	0	0	0	0	1	0	0	0	0	0	1
Meningioma	0	0	0	1	0	0	0	0	0	0	1
Metastatic breast cancer	0	0	0	0	0	0	0	0	1	0	1
Mole	0	0	0	0	0	1	0	0	0	0	1
Non-small cell lung cancer	0	0	0	0	0	1	0	0	0	0	1
Second primary BC	0	0	0	0	0	0	0	0	1	2	3
<b>Nervous system disorders</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>6</b>	<b>6</b>	<b>6</b>	<b>3</b>	<b>0</b>	<b>4</b>	<b>1</b>	<b>27</b>



	0	1-30	31-60	61-180	181-365	366-730	731-1095	1096-1460	1461-1825	>1825	Total
Dry skin	0	0	0	0	1	0	0	0	0	0	1
Erythema multiforme	2	3	0	1	0	1	0	0	0	0	7
Hirsutism	0	0	0	0	1	0	0	0	0	0	1
Pruritus	0	4	0	1	0	0	0	0	1	0	6
Rash acneiform	0	1	0	0	0	0	0	0	0	0	1
Skin hyperpigmentation	0	0	0	0	1	0	0	0	0	0	1
Skin rash	0	1	0	0	0	0	0	0	0	0	1
<b>Surgical and medical procedures</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>2</b>
Herniorrhaphy /Hernioplasty	0	0	0	0	0	0	0	0	1	0	1
Yellow discharge	0	1	0	0	0	0	0	0	0	0	1
<b>Vascular disorders</b>	<b>8</b>	<b>3</b>	<b>0</b>	<b>4</b>	<b>5</b>	<b>2</b>	<b>4</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>27</b>
Bilateral Carotid Stenosis	0	0	0	0	0	0	1	0	0	0	1
Flushing	1	0	0	0	0	0	0	0	0	0	1
Hematoma	7	2	0	0	0	0	0	0	0	0	9
Hot flashes	0	1	0	2	4	0	1	1	0	0	9
Hypertension	0	0	0	1	0	1	2	0	0	0	4
Thromboembolic event	0	0	0	1	1	1	0	0	0	0	3

Adverse events with missing date are analyzed as relative day 1.  
Source: Tables Safety by Severity-Timecourse\_FAS.sas; Analyzed: 09JUN2024

**Table 34: All Adverse Events by AE Code and Severity – Primary Analysis Set**

	Mild		Moderate		Severe		Total
	Events	%*	Events	%*	Events	%*	Events
<b>All Events</b>	<b>333</b>	<b>64.4%</b>	<b>92</b>	<b>17.8%</b>	<b>92</b>	<b>17.8%</b>	<b>517</b>
<b>Blood and lymphatic system disorders</b>	<b>1</b>	<b>14.3%</b>	<b>3</b>	<b>42.9%</b>	<b>3</b>	<b>42.9%</b>	<b>7</b>
Anemia	0	0.0%	0	0.0%	1	100.0%	1
Febrile Neutropenia	0	0.0%	0	0.0%	2	100.0%	2
Leukocytosis	0	0.0%	2	100.0%	0	0.0%	2
Lymph node pain	1	50.0%	1	50.0%	0	0.0%	2
<b>Cardiac disorders</b>	<b>6</b>	<b>26.1%</b>	<b>4</b>	<b>17.4%</b>	<b>13</b>	<b>56.5%</b>	<b>23</b>
Acute coronary syndrome	1	100.0%	0	0.0%	0	0.0%	1
Aortic valve disease	0	0.0%	0	0.0%	1	100.0%	1
Atrial fibrillation	1	25.0%	2	50.0%	1	25.0%	4
Atrial flutter	1	100.0%	0	0.0%	0	0.0%	1
Atrioventricular Block Complete	0	0.0%	0	0.0%	1	100.0%	1
Cardiac arrest	0	0.0%	0	0.0%	2	100.0%	2
Chest pain - cardiac	0	0.0%	0	0.0%	2	100.0%	2
Heart failure	0	0.0%	2	40.0%	3	60.0%	5
Myocardial infarction	0	0.0%	0	0.0%	2	100.0%	2
Palpitations	3	100.0%	0	0.0%	0	0.0%	3
Sick sinus syndrome	0	0.0%	0	0.0%	1	100.0%	1
<b>Ear and labyrinth disorders</b>	<b>3</b>	<b>60.0%</b>	<b>2</b>	<b>40.0%</b>	<b>0</b>	<b>0.0%</b>	<b>5</b>
Ear Pain	0	0.0%	1	100.0%	0	0.0%	1
Hearing impaired	2	100.0%	0	0.0%	0	0.0%	2
Tinnitus	1	100.0%	0	0.0%	0	0.0%	1

	Mild		Moderate		Severe		Total
	Events	%*	Events	%*	Events	%*	Events
Vestibular Disorder	0	0.0%	1	100.0%	0	0.0%	1
<b>Eye disorders</b>	<b>1</b>	<b>50.0%</b>	<b>1</b>	<b>50.0%</b>	<b>0</b>	<b>0.0%</b>	<b>2</b>
Cataract	1	100.0%	0	0.0%	0	0.0%	1
Macular degeneration	0	0.0%	1	100.0%	0	0.0%	1
<b>Gastrointestinal disorders</b>	<b>10</b>	<b>43.5%</b>	<b>5</b>	<b>21.7%</b>	<b>8</b>	<b>34.8%</b>	<b>23</b>
Abdominal Distension	1	100.0%	0	0.0%	0	0.0%	1
Abdominal pain	2	50.0%	1	25.0%	1	25.0%	4
Colitis	0	0.0%	0	0.0%	1	100.0%	1
Constipation	4	57.1%	1	14.3%	2	28.6%	7
Diarrhea	2	66.7%	0	0.0%	1	33.3%	3
Duodenal hemorrhage	0	0.0%	1	100.0%	0	0.0%	1
Dyspepsia	1	100.0%	0	0.0%	0	0.0%	1
Dysphagia	0	0.0%	0	0.0%	1	100.0%	1
Obstruction gastric	0	0.0%	0	0.0%	2	100.0%	2
Sigmoid diverticulitis	0	0.0%	1	100.0%	0	0.0%	1
Small intestinal obstruction	0	0.0%	1	100.0%	0	0.0%	1
<b>General disorders and administration site conditions</b>	<b>111</b>	<b>88.8%</b>	<b>7</b>	<b>5.6%</b>	<b>7</b>	<b>5.6%</b>	<b>125</b>
COVID	0	0.0%	1	33.3%	2	66.7%	3
Chills	1	100.0%	0	0.0%	0	0.0%	1
Death NOS	0	0.0%	0	0.0%	3	100.0%	3
Edema limbs	1	50.0%	0	0.0%	1	50.0%	2
Edema of limbs	0	0.0%	1	100.0%	0	0.0%	1
Fatigue	14	93.3%	1	6.7%	0	0.0%	15
Heat sensation	2	100.0%	0	0.0%	0	0.0%	2
Infusion site extravasation	1	100.0%	0	0.0%	0	0.0%	1
Injection site reaction	11	100.0%	0	0.0%	0	0.0%	11
Irritability	1	100.0%	0	0.0%	0	0.0%	1
Localized edema	35	92.1%	3	7.9%	0	0.0%	38
Malaise	1	100.0%	0	0.0%	0	0.0%	1
Multi-organ failure	0	0.0%	0	0.0%	1	100.0%	1
Non-cardiac chest pain	2	100.0%	0	0.0%	0	0.0%	2
Pain	42	97.7%	1	2.3%	0	0.0%	43
<b>Infections and infestations</b>	<b>12</b>	<b>38.7%</b>	<b>9</b>	<b>29.0%</b>	<b>10</b>	<b>32.3%</b>	<b>31</b>
Endocarditis infective	0	0.0%	0	0.0%	1	100.0%	1
Lung infection	2	33.3%	1	16.7%	3	50.0%	6
Papulopustular Rash	0	0.0%	1	100.0%	0	0.0%	1
Rash Pustular	1	100.0%	0	0.0%	0	0.0%	1
Sepsis	0	0.0%	0	0.0%	3	100.0%	3
Skin infection	8	53.3%	6	40.0%	1	6.7%	15
Upper respiratory infection	0	0.0%	1	100.0%	0	0.0%	1
Urinary tract infection	1	33.3%	0	0.0%	2	66.7%	3
<b>Injury, poisoning and procedural complications</b>	<b>58</b>	<b>75.3%</b>	<b>14</b>	<b>18.2%</b>	<b>5</b>	<b>6.5%</b>	<b>77</b>
Bruising	45	78.9%	9	15.8%	3	5.3%	57
Burn	2	50.0%	2	50.0%	0	0.0%	4
Dermatitis radiation	2	66.7%	1	33.3%	0	0.0%	3
Fall	6	75.0%	1	12.5%	1	12.5%	8
Fracture	2	66.7%	1	33.3%	0	0.0%	3
Hip fracture	0	0.0%	0	0.0%	1	100.0%	1
postoperative hemorrhage	1	100.0%	0	0.0%	0	0.0%	1

	Mild		Moderate		Severe		Total
	Events	%*	Events	%*	Events	%*	Events
<b>Investigations</b>	<b>2</b>	<b>50.0%</b>	<b>2</b>	<b>50.0%</b>	<b>0</b>	<b>0.0%</b>	<b>4</b>
Cholesterol high	0	0.0%	1	100.0%	0	0.0%	1
Weight loss	2	66.7%	1	33.3%	0	0.0%	3
<b>Metabolism and nutrition disorders</b>	<b>2</b>	<b>40.0%</b>	<b>1</b>	<b>20.0%</b>	<b>2</b>	<b>40.0%</b>	<b>5</b>
Anorexia	1	100.0%	0	0.0%	0	0.0%	1
Hypercalcemia	0	0.0%	0	0.0%	1	100.0%	1
Hypertriglyceridemia	1	100.0%	0	0.0%	0	0.0%	1
Hypokalemia	0	0.0%	0	0.0%	1	100.0%	1
Malnutrition	0	0.0%	1	100.0%	0	0.0%	1
<b>Musculoskeletal and connective tissue disorders</b>	<b>35</b>	<b>77.8%</b>	<b>9</b>	<b>20.0%</b>	<b>1</b>	<b>2.2%</b>	<b>45</b>
Arthralgia	13	81.3%	3	18.8%	0	0.0%	16
Arthritis	1	33.3%	1	33.3%	1	33.3%	3
Back pain	6	85.7%	1	14.3%	0	0.0%	7
Flank Pain	1	100.0%	0	0.0%	0	0.0%	1
Generalized muscle weakness	1	100.0%	0	0.0%	0	0.0%	1
Myalgia	3	75.0%	1	25.0%	0	0.0%	4
Neck pain	2	100.0%	0	0.0%	0	0.0%	2
Osteoporosis	1	100.0%	0	0.0%	0	0.0%	1
Pain in extremity	6	85.7%	1	14.3%	0	0.0%	7
Rhabdomyolysis	1	100.0%	0	0.0%	0	0.0%	1
Superficial soft tissue fibrosis	0	0.0%	2	100.0%	0	0.0%	2
<b>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</b>	<b>3</b>	<b>12.0%</b>	<b>12</b>	<b>48.0%</b>	<b>10</b>	<b>40.0%</b>	<b>25</b>
Acute Myeloid Leukemia	0	0.0%	0	0.0%	1	100.0%	1
Benign Neoplasm	0	0.0%	1	100.0%	0	0.0%	1
DCIS Left Breast	0	0.0%	0	0.0%	1	100.0%	1
Diffuse Metastatic disease to the bones	0	0.0%	0	0.0%	1	100.0%	1
Endometrial Cancer	0	0.0%	1	50.0%	1	50.0%	2
Endometrial Cyst	1	100.0%	0	0.0%	0	0.0%	1
Epidermal Inclusion Cyst	1	100.0%	0	0.0%	0	0.0%	1
Hepatocellular carcinoma	0	0.0%	0	0.0%	1	100.0%	1
Kidney cancer	0	0.0%	0	0.0%	1	100.0%	1
Local recurrence	0	0.0%	7	100.0%	0	0.0%	7
Lung Adenocarcinoma	0	0.0%	1	100.0%	0	0.0%	1
Meningioma	0	0.0%	0	0.0%	1	100.0%	1
Metastatic breast cancer	0	0.0%	0	0.0%	1	100.0%	1
Mole	1	100.0%	0	0.0%	0	0.0%	1
Non-small cell lung cancer	0	0.0%	0	0.0%	1	100.0%	1
Second primary BC	0	0.0%	2	66.7%	1	33.3%	3
<b>Nervous system disorders</b>	<b>12</b>	<b>44.4%</b>	<b>6</b>	<b>22.2%</b>	<b>9</b>	<b>33.3%</b>	<b>27</b>
Altered mental status	0	0.0%	0	0.0%	1	100.0%	1
Dizziness	3	75.0%	1	25.0%	0	0.0%	4
Encephalopathy	0	0.0%	0	0.0%	1	100.0%	1
Headache	2	66.7%	1	33.3%	0	0.0%	3
Intracranial hemorrhage	0	0.0%	0	0.0%	1	100.0%	1
Memory impairment	4	66.7%	0	0.0%	2	33.3%	6
Paresthesia	1	50.0%	1	50.0%	0	0.0%	2
Peripheral sensory neuropathy	1	100.0%	0	0.0%	0	0.0%	1
Presyncope	0	0.0%	1	100.0%	0	0.0%	1
Seizure	0	0.0%	1	100.0%	0	0.0%	1

	Mild		Moderate		Severe		Total
	Events	%*	Events	%*	Events	%*	Events
Spasticity	1	100.0%	0	0.0%	0	0.0%	1
Stroke	0	0.0%	1	50.0%	1	50.0%	2
Syncope	0	0.0%	0	0.0%	1	100.0%	1
Thoracic stenosis	0	0.0%	0	0.0%	1	100.0%	1
Transient ischemic attacks	0	0.0%	0	0.0%	1	100.0%	1
<b>Psychiatric disorders</b>	<b>14</b>	<b>100.0%</b>	<b>0</b>	<b>0.0%</b>	<b>0</b>	<b>0.0%</b>	<b>14</b>
Anxiety	6	100.0%	0	0.0%	0	0.0%	6
Depression	3	100.0%	0	0.0%	0	0.0%	3
Insomnia	4	100.0%	0	0.0%	0	0.0%	4
Psychiatric disorders - Other Mild	1	100.0%	0	0.0%	0	0.0%	1
<b>Renal and urinary disorders</b>	<b>6</b>	<b>54.5%</b>	<b>2</b>	<b>18.2%</b>	<b>3</b>	<b>27.3%</b>	<b>11</b>
Acute kidney injury	0	0.0%	1	25.0%	3	75.0%	4
Hematuria	1	100.0%	0	0.0%	0	0.0%	1
Urinary frequency	2	100.0%	0	0.0%	0	0.0%	2
Urinary incontinence	2	66.7%	1	33.3%	0	0.0%	3
urinary tract pain	1	100.0%	0	0.0%	0	0.0%	1
<b>Reproductive system and breast disorders</b>	<b>6</b>	<b>100.0%</b>	<b>0</b>	<b>0.0%</b>	<b>0</b>	<b>0.0%</b>	<b>6</b>
Breast twitches	1	100.0%	0	0.0%	0	0.0%	1
Dimpling	1	100.0%	0	0.0%	0	0.0%	1
Dyspareunia	1	100.0%	0	0.0%	0	0.0%	1
Tethering	1	100.0%	0	0.0%	0	0.0%	1
Vaginal dryness	2	100.0%	0	0.0%	0	0.0%	2
<b>Respiratory, thoracic and mediastinal disorders</b>	<b>14</b>	<b>37.8%</b>	<b>7</b>	<b>18.9%</b>	<b>16</b>	<b>43.2%</b>	<b>37</b>
Aspiration	1	50.0%	0	0.0%	1	50.0%	2
Atelectasis	1	100.0%	0	0.0%	0	0.0%	1
COPD	1	50.0%	0	0.0%	1	50.0%	2
Cough	6	100.0%	0	0.0%	0	0.0%	6
Dyspnea	4	36.4%	2	18.2%	5	45.5%	11
Emphysema	0	0.0%	0	0.0%	1	100.0%	1
Hypoxia	0	0.0%	1	50.0%	1	50.0%	2
Nasal congestion	1	100.0%	0	0.0%	0	0.0%	1
Pleural effusion	0	0.0%	4	66.7%	2	33.3%	6
Pulmonary edema	0	0.0%	0	0.0%	1	100.0%	1
Respiratory failure	0	0.0%	0	0.0%	4	100.0%	4
<b>Skin and subcutaneous tissue disorders</b>	<b>18</b>	<b>85.7%</b>	<b>3</b>	<b>14.3%</b>	<b>0</b>	<b>0.0%</b>	<b>21</b>
Alopecia	1	100.0%	0	0.0%	0	0.0%	1
Body odor	1	100.0%	0	0.0%	0	0.0%	1
Drainage	1	100.0%	0	0.0%	0	0.0%	1
Dry skin	1	100.0%	0	0.0%	0	0.0%	1
Erythema multiforme	5	71.4%	2	28.6%	0	0.0%	7
Hirsutism	1	100.0%	0	0.0%	0	0.0%	1
Pruritus	6	100.0%	0	0.0%	0	0.0%	6
Rash acneiform	1	100.0%	0	0.0%	0	0.0%	1
Skin hyperpigmentation	0	0.0%	1	100.0%	0	0.0%	1
Skin rash	1	100.0%	0	0.0%	0	0.0%	1
<b>Surgical and medical procedures</b>	<b>1</b>	<b>50.0%</b>	<b>1</b>	<b>50.0%</b>	<b>0</b>	<b>0.0%</b>	<b>2</b>
Herniorrhaphy /Hernioplasty	0	0.0%	1	100.0%	0	0.0%	1
Yellow discharge	1	100.0%	0	0.0%	0	0.0%	1
<b>Vascular disorders</b>	<b>18</b>	<b>66.7%</b>	<b>4</b>	<b>14.8%</b>	<b>5</b>	<b>18.5%</b>	<b>27</b>

	Mild		Moderate		Severe		Total
	Events	%*	Events	%*	Events	%*	Events
Bilateral Carotid Stenosis	0	0.0%	1	100.0%	0	0.0%	1
Flushing	1	100.0%	0	0.0%	0	0.0%	1
Hematoma	8	88.9%	1	11.1%	0	0.0%	9
Hot flashes	8	88.9%	0	0.0%	1	11.1%	9
Hypertension	1	25.0%	1	25.0%	2	50.0%	4
Thromboembolic event	0	0.0%	1	33.3%	2	66.7%	3

\*Percentage of total events.

Source: Tables Safety by Severity-Timecourse\_FAS.sas; Analyzed: 09JUN2024

**Table 35: All Procedure Related Adverse Events– Primary Analysis Set (N=194)**

	ICECURE (N= 194)			Kaplan-Meier**			
	Events†	Subjs‡	%°	Year 2	Year 5	Year 2 1-sided 95% CI UB	Year 5 1-sided 95% CI UB
<b>All Events</b>	<b>180</b>	<b>93</b>	<b>47.9%</b>	<b>46.9%</b>	<b>48.2%</b>	<b>53.0%</b>	<b>54.2%</b>
<b>General disorders and administration site conditions</b>	<b>91</b>	<b>67</b>	<b>34.5%</b>	<b>34.6%</b>	<b>34.6%</b>	<b>40.6%</b>	<b>40.6%</b>
Fatigue	2	2	1.0%	1.0%	1.0%	3.3%	3.3%
Heat sensation	1	1	0.5%	0.5%	0.5%	2.8%	2.8%
Infusion site extravasation	1	1	0.5%	0.5%	0.5%	2.6%	2.6%
Injection site reaction	11	10	5.2%	5.2%	5.2%	8.6%	8.6%
Localized edema	37	36	18.6%	18.6%	18.6%	23.7%	23.7%
Non-cardiac chest pain	1	1	0.5%	0.5%	0.5%	2.6%	2.6%
Pain	38	36	18.6%	18.1%	18.8%	23.1%	23.9%
<b>Injury, poisoning and procedural complications</b>	<b>62</b>	<b>59</b>	<b>30.4%</b>	<b>30.4%</b>	<b>30.4%</b>	<b>36.2%</b>	<b>36.2%</b>
Bruising	57	57	29.4%	29.4%	29.4%	35.1%	35.1%
Burn	4	4	2.1%	2.1%	2.1%	4.6%	4.6%
postoperative hemorrhage	1	1	0.5%	0.5%	0.5%	2.6%	2.6%
<b>Musculoskeletal and connective tissue disorders</b>	<b>1</b>	<b>1</b>	<b>0.5%</b>	<b>0.5%</b>	<b>0.5%</b>	<b>2.6%</b>	<b>2.6%</b>
Pain in extremity	1	1	0.5%	0.5%	0.5%	2.6%	2.6%
<b>Neoplasms benign, malignant and unspecified (incl cysts and p</b>	<b>4</b>	<b>3</b>	<b>1.5%</b>	<b>0.0%</b>	<b>1.9%</b>	<b>0.0%</b>	<b>4.9%</b>
Local recurrence	3	3	1.5%	0.0%	1.9%	0.0%	4.9%
Metastatic breast cancer	1	1	0.5%	0.0%	0.7%	0.0%	3.6%
<b>Reproductive system and breast disorders</b>	<b>3</b>	<b>2</b>	<b>1.0%</b>	<b>1.0%</b>	<b>1.0%</b>	<b>3.3%</b>	<b>3.3%</b>
Breast twitches	1	1	0.5%	0.5%	0.5%	2.6%	2.6%
Dimpling	1	1	0.5%	0.5%	0.5%	2.7%	2.7%
Tethering	1	1	0.5%	0.5%	0.5%	2.7%	2.7%
<b>Skin and subcutaneous tissue disorders</b>	<b>8</b>	<b>8</b>	<b>4.1%</b>	<b>4.1%</b>	<b>4.1%</b>	<b>7.3%</b>	<b>7.3%</b>
Drainage	1	1	0.5%	0.5%	0.5%	2.6%	2.6%
Erythema multiforme	3	3	1.5%	1.5%	1.5%	3.9%	3.9%
Pruritus	3	3	1.5%	1.5%	1.5%	3.9%	3.9%
Rash acneiform	1	1	0.5%	0.5%	0.5%	2.6%	2.6%
<b>Surgical and medical procedures</b>	<b>1</b>	<b>1</b>	<b>0.5%</b>	<b>0.5%</b>	<b>0.5%</b>	<b>2.6%</b>	<b>2.6%</b>
Yellow discharge	1	1	0.5%	0.5%	0.5%	2.6%	2.6%
<b>Vascular disorders</b>	<b>10</b>	<b>10</b>	<b>5.2%</b>	<b>5.2%</b>	<b>5.2%</b>	<b>8.5%</b>	<b>8.5%</b>
Flushing	1	1	0.5%	0.5%	0.5%	2.6%	2.6%
Hematoma	9	9	4.6%	4.6%	4.6%	7.9%	7.9%

† Total number of events without regard to length of follow-up.  
‡ Number of subjects experiencing event without regard to length of follow-up.  
° Percentage of subjects experiencing specific event without regard to length of follow-up.  
\*\* Kaplan-Meier Estimates at day 365, 730, 1095, 1460, and 1825 with 1-sided 95% CI upper bound (UB).  
Procedure relationship: Remotely, Possible, Probable, Unknown.  
Adverse events with missing date are analyzed as relative day 1.  
Source: Tables Safety\_FAS.sas; Analyzed: 09JUN2024

**Table 36: All Procedure Related Adverse Events by High Term – Primary Analysis Set (N=194)**

	ICECURE (N= 194)			Kaplan-Meier**			
	Events†	Subjs‡	%°	Year 2	Year 5	Year 2 1-sided 95% CI UB	Year 5 1-sided 95% CI UB
<b>All Events</b>	<b>180</b>	<b>93</b>	<b>47.9%</b>	<b>46.9%</b>	<b>48.2%</b>	<b>53.0%</b>	<b>54.2%</b>
<b>General disorders and administration site conditions</b>	<b>91</b>	<b>67</b>	<b>34.5%</b>	<b>34.6%</b>	<b>34.6%</b>	<b>40.6%</b>	<b>40.6%</b>
<b>Injury, poisoning and procedural complications</b>	<b>62</b>	<b>59</b>	<b>30.4%</b>	<b>30.4%</b>	<b>30.4%</b>	<b>36.2%</b>	<b>36.2%</b>
<b>Musculoskeletal and connective tissue disorders</b>	<b>1</b>	<b>1</b>	<b>0.5%</b>	<b>0.5%</b>	<b>0.5%</b>	<b>2.6%</b>	<b>2.6%</b>
<b>Neoplasms benign, malignant and unspecified (incl cysts and p</b>	<b>4</b>	<b>3</b>	<b>1.5%</b>	<b>0.0%</b>	<b>1.9%</b>	<b>0.0%</b>	<b>4.9%</b>
<b>Reproductive system and breast disorders</b>	<b>3</b>	<b>2</b>	<b>1.0%</b>	<b>1.0%</b>	<b>1.0%</b>	<b>3.3%</b>	<b>3.3%</b>
<b>Skin and subcutaneous tissue disorders</b>	<b>8</b>	<b>8</b>	<b>4.1%</b>	<b>4.1%</b>	<b>4.1%</b>	<b>7.3%</b>	<b>7.3%</b>
<b>Surgical and medical procedures</b>	<b>1</b>	<b>1</b>	<b>0.5%</b>	<b>0.5%</b>	<b>0.5%</b>	<b>2.6%</b>	<b>2.6%</b>
<b>Vascular disorders</b>	<b>10</b>	<b>10</b>	<b>5.2%</b>	<b>5.2%</b>	<b>5.2%</b>	<b>8.5%</b>	<b>8.5%</b>

† Total number of events without regard to length of follow-up.  
‡ Number of subjects experiencing event without regard to length of follow-up.  
° Percentage of subjects experiencing specific event without regard to length of follow-up.  
\*\* Kaplan-Meier Estimates at day 365, 730, 1095, 1460, and 1825 with 1-sided 95% CI upper bound (UB).  
Procedure relationship: Remotely, Possible, Probable, Unknown.  
Adverse events with missing date are analyzed as relative day 1.  
Source: Tables Safety\_FAS.sas; Analyzed: 09JUN2024

**Table 37: All Procedure Related Adverse Events by AE Code and Timecourse – Primary Analysis Set**

	Days Post-Op										Total
	0	1-30	31-60	61-180	181-365	366-730	731-1095	1096-1460	1461-1825	>1825	
<b>All Events</b>	<b>62</b>	<b>102</b>	<b>1</b>	<b>1</b>	<b>6</b>	<b>3</b>	<b>2</b>	<b>1</b>	<b>2</b>	<b>0</b>	<b>180</b>
<b>General disorders and administration site conditions</b>	<b>34</b>	<b>47</b>	<b>1</b>	<b>1</b>	<b>4</b>	<b>3</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>91</b>
Fatigue	1	1	0	0	0	0	0	0	0	0	2
Heat sensation	0	0	0	0	0	1	0	0	0	0	1
Infusion site extravasation	0	1	0	0	0	0	0	0	0	0	1
Injection site reaction	3	6	0	0	0	2	0	0	0	0	11
Localized edema	11	24	0	1	1	0	0	0	0	0	37
Non-cardiac chest pain	1	0	0	0	0	0	0	0	0	0	1
Pain	18	15	1	0	3	0	0	1	0	0	38
<b>Injury, poisoning and procedural complications</b>	<b>18</b>	<b>44</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>62</b>
Bruising	16	41	0	0	0	0	0	0	0	0	57
Burn	1	3	0	0	0	0	0	0	0	0	4
postoperative hemorrhage	1	0	0	0	0	0	0	0	0	0	1
<b>Musculoskeletal and connective tissue disorders</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>
Pain in extremity	1	0	0	0	0	0	0	0	0	0	1
<b>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>2</b>	<b>0</b>	<b>2</b>	<b>0</b>	<b>4</b>
Local recurrence	0	0	0	0	0	0	2	0	1	0	3
Metastatic breast cancer	0	0	0	0	0	0	0	0	1	0	1
<b>Reproductive system and breast disorders</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>2</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>3</b>
Breast twitches	0	1	0	0	0	0	0	0	0	0	1
Dimpling	0	0	0	0	1	0	0	0	0	0	1

	Days Post-Op										Total
	0	1-30	31-60	61-180	181-365	366-730	731-1095	1096-1460	1461-1825	>1825	
Tethering	0	0	0	0	1	0	0	0	0	0	1
<b>Skin and subcutaneous tissue disorders</b>	<b>1</b>	<b>7</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>8</b>
Drainage	0	1	0	0	0	0	0	0	0	0	1
Erythema multiforme	1	2	0	0	0	0	0	0	0	0	3
Pruritus	0	3	0	0	0	0	0	0	0	0	3
Rash acneiform	0	1	0	0	0	0	0	0	0	0	1
<b>Surgical and medical procedures</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>
Yellow discharge	0	1	0	0	0	0	0	0	0	0	1
<b>Vascular disorders</b>	<b>8</b>	<b>2</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>10</b>
Flushing	1	0	0	0	0	0	0	0	0	0	1
Hematoma	7	2	0	0	0	0	0	0	0	0	9

†Defined as Remotely/Possible/Probable and Unknown.  
Adverse events with missing date are analyzed as relative day 1.  
Source: Tables Safety by Severity-Timecourse\_FAS.sas; Analyzed: 09JUN2024

**Table 38: All Procedure Related Adverse Events by AE Code and Severity – Primary Analysis Set**

	Mild		Moderate		Severe		Total
	Events	%*	Events	%*	Events	%*	Events
<b>All Events</b>	<b>158</b>	<b>87.8%</b>	<b>18</b>	<b>10.0%</b>	<b>4</b>	<b>2.2%</b>	<b>180</b>
<b>General disorders and administration site conditions</b>	<b>88</b>	<b>96.7%</b>	<b>3</b>	<b>3.3%</b>	<b>0</b>	<b>0.0%</b>	<b>91</b>
Fatigue	2	100.0%	0	0.0%	0	0.0%	2
Heat sensation	1	100.0%	0	0.0%	0	0.0%	1
Infusion site extravasation	1	100.0%	0	0.0%	0	0.0%	1
Injection site reaction	11	100.0%	0	0.0%	0	0.0%	11
Localized edema	35	94.6%	2	5.4%	0	0.0%	37
Non-cardiac chest pain	1	100.0%	0	0.0%	0	0.0%	1
Pain	37	97.4%	1	2.6%	0	0.0%	38
<b>Injury, poisoning and procedural complications</b>	<b>48</b>	<b>77.4%</b>	<b>11</b>	<b>17.7%</b>	<b>3</b>	<b>4.8%</b>	<b>62</b>
Bruising	45	78.9%	9	15.8%	3	5.3%	57
Burn	2	50.0%	2	50.0%	0	0.0%	4
postoperative hemorrhage	1	100.0%	0	0.0%	0	0.0%	1
<b>Musculoskeletal and connective tissue disorders</b>	<b>1</b>	<b>100.0%</b>	<b>0</b>	<b>0.0%</b>	<b>0</b>	<b>0.0%</b>	<b>1</b>
Pain in extremity	1	100.0%	0	0.0%	0	0.0%	1
<b>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</b>	<b>0</b>	<b>0.0%</b>	<b>3</b>	<b>75.0%</b>	<b>1</b>	<b>25.0%</b>	<b>4</b>
Local recurrence	0	0.0%	3	100.0%	0	0.0%	3
Metastatic breast cancer	0	0.0%	0	0.0%	1	100.0%	1
<b>Reproductive system and breast disorders</b>	<b>3</b>	<b>100.0%</b>	<b>0</b>	<b>0.0%</b>	<b>0</b>	<b>0.0%</b>	<b>3</b>
Breast twitches	1	100.0%	0	0.0%	0	0.0%	1
Dimpling	1	100.0%	0	0.0%	0	0.0%	1
Tethering	1	100.0%	0	0.0%	0	0.0%	1
<b>Skin and subcutaneous tissue disorders</b>	<b>8</b>	<b>100.0%</b>	<b>0</b>	<b>0.0%</b>	<b>0</b>	<b>0.0%</b>	<b>8</b>

Drainage	1	100.0%	0	0.0%	0	0.0%	1
Erythema multiforme	3	100.0%	0	0.0%	0	0.0%	3
Pruritus	3	100.0%	0	0.0%	0	0.0%	3
Rash acneiform	1	100.0%	0	0.0%	0	0.0%	1
<b>Surgical and medical procedures</b>	<b>1</b>	<b>100.0%</b>	<b>0</b>	<b>0.0%</b>	<b>0</b>	<b>0.0%</b>	<b>1</b>
Yellow discharge	1	100.0%	0	0.0%	0	0.0%	1
<b>Vascular disorders</b>	<b>9</b>	<b>90.0%</b>	<b>1</b>	<b>10.0%</b>	<b>0</b>	<b>0.0%</b>	<b>10</b>
Flushing	1	100.0%	0	0.0%	0	0.0%	1
Hematoma	8	88.9%	1	11.1%	0	0.0%	9

\*Percentage of total events. †Defined as Remotely/Possible/Probable and Unknown.

Source: Tables Safety by Severity-Timecourse\_FAS.sas; Analyzed: 09JUN2024

**Table 39: All Serious Adverse Events by High and Low Terms – Primary Analysis Set (N=194)**

	ICECURE (N= 194)			Kaplan-Meier**			
	Events†	Subjs‡	%°	Year 2	Year 5	Year 2 1-sided 95% CI UB	Year 5 1-sided 95% CI UB
<b>All Events</b>	<b>127</b>	<b>59</b>	<b>30.4%</b>	<b>9.9%</b>	<b>31.5%</b>	<b>14.2%</b>	<b>37.7%</b>
<b>Blood and lymphatic system disorders</b>	<b>4</b>	<b>4</b>	<b>2.1%</b>	<b>1.0%</b>	<b>2.5%</b>	<b>3.3%</b>	<b>5.7%</b>
Anemia	1	1	0.5%	0.0%	0.8%	0.0%	3.9%
Febrile Neutropenia	2	2	1.0%	0.5%	1.2%	2.7%	3.9%
Leukocytosis	1	1	0.5%	0.5%	0.5%	2.7%	2.7%
<b>Cardiac disorders</b>	<b>18</b>	<b>13</b>	<b>6.7%</b>	<b>1.6%</b>	<b>7.7%</b>	<b>4.2%</b>	<b>11.9%</b>
Acute coronary syndrome	1	1	0.5%	0.0%	0.6%	0.0%	3.3%
Aortic valve disease	1	1	0.5%	0.0%	0.6%	0.0%	3.0%
Atrial fibrillation	2	2	1.0%	0.0%	0.6%	0.0%	3.0%
Atrioventricular Block Complete	1	1	0.5%	0.0%	0.6%	0.0%	3.1%
Cardiac arrest	2	2	1.0%	0.0%	1.2%	0.0%	3.9%
Chest pain - cardiac	2	1	0.5%	0.0%	0.7%	0.0%	3.5%
Heart failure	5	4	2.1%	0.5%	2.5%	2.7%	5.5%
Myocardial infarction	2	2	1.0%	0.5%	1.2%	2.8%	3.8%
Palpitations	1	1	0.5%	0.6%	0.6%	2.9%	2.9%
Sick sinus syndrome	1	1	0.5%	0.0%	0.6%	0.0%	3.3%

	ICECURE (N= 194)			Kaplan-Meier**			
	Events†	Subjs‡	%°	Year 2	Year 5	Year 2 1-sided 95% CI UB	Year 5 1-sided 95% CI UB
<b>Ear and labyrinth disorders</b>	<b>1</b>	<b>1</b>	<b>0.5%</b>	<b>0.5%</b>	<b>0.5%</b>	<b>2.7%</b>	<b>2.7%</b>
Vestibular Disorder	1	1	0.5%	0.5%	0.5%	2.7%	2.7%
<b>Gastrointestinal disorders</b>	<b>10</b>	<b>9</b>	<b>4.6%</b>	<b>1.1%</b>	<b>5.9%</b>	<b>3.3%</b>	<b>10.0%</b>
Abdominal pain	1	1	0.5%	0.0%	0.7%	0.0%	3.4%
Colitis	1	1	0.5%	0.5%	0.5%	2.7%	2.7%
Constipation	2	2	1.0%	0.5%	1.2%	2.7%	3.9%
Duodenal hemorrhage	1	1	0.5%	0.0%	0.6%	0.0%	3.3%
Dysphagia	1	1	0.5%	0.0%	0.7%	0.0%	3.8%
Obstruction gastric	2	1	0.5%	0.0%	0.6%	0.0%	3.3%
Sigmoid diverticulitis	1	1	0.5%	0.0%	0.8%	0.0%	4.0%
Small intestinal obstruction	1	1	0.5%	0.0%	0.7%	0.0%	3.5%
<b>General disorders and administration site conditions</b>	<b>8</b>	<b>6</b>	<b>3.1%</b>	<b>0.6%</b>	<b>3.8%</b>	<b>2.8%</b>	<b>7.3%</b>
COVID	3	2	1.0%	0.0%	1.4%	0.0%	4.3%
Death NOS	3	3	1.5%	0.0%	1.9%	0.0%	4.8%
Edema limbs	1	1	0.5%	0.0%	0.7%	0.0%	3.6%
Multi-organ failure	1	1	0.5%	0.6%	0.6%	2.8%	2.8%
<b>Infections and infestations</b>	<b>16</b>	<b>13</b>	<b>6.7%</b>	<b>2.7%</b>	<b>6.5%</b>	<b>5.5%</b>	<b>10.4%</b>
Endocarditis infective	1	1	0.5%	0.0%	0.6%	0.0%	3.0%
Lung infection	5	5	2.6%	0.0%	2.1%	0.0%	5.4%
Sepsis	3	3	1.5%	0.6%	2.0%	2.8%	5.0%
Skin infection	4	3	1.5%	1.6%	1.6%	4.1%	4.1%
Upper respiratory infection	1	1	0.5%	0.0%	0.8%	0.0%	3.9%
Urinary tract infection	2	2	1.0%	0.5%	1.1%	2.7%	3.5%
<b>Injury, poisoning and procedural complications</b>	<b>4</b>	<b>4</b>	<b>2.1%</b>	<b>0.6%</b>	<b>1.9%</b>	<b>2.9%</b>	<b>4.9%</b>
Fall	2	2	1.0%	0.0%	0.7%	0.0%	3.5%
Fracture	1	1	0.5%	0.6%	0.6%	2.9%	2.9%
Hip fracture	1	1	0.5%	0.0%	0.7%	0.0%	3.4%
<b>Metabolism and nutrition disorders</b>	<b>3</b>	<b>3</b>	<b>1.5%</b>	<b>0.5%</b>	<b>1.2%</b>	<b>2.7%</b>	<b>3.8%</b>
Hypercalcemia	1	1	0.5%	0.5%	0.5%	2.7%	2.7%
Hypokalemia	1	1	0.5%	0.0%	0.0%	0.0%	0.0%
Malnutrition	1	1	0.5%	0.0%	0.7%	0.0%	3.4%
<b>Musculoskeletal and connective tissue disorders</b>	<b>2</b>	<b>2</b>	<b>1.0%</b>	<b>0.0%</b>	<b>1.3%</b>	<b>0.0%</b>	<b>4.2%</b>
Arthritis	1	1	0.5%	0.0%	0.7%	0.0%	3.5%
Rhabdomyolysis	1	1	0.5%	0.0%	0.6%	0.0%	3.3%
<b>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</b>	<b>21</b>	<b>20</b>	<b>10.3%</b>	<b>1.6%</b>	<b>11.4%</b>	<b>4.1%</b>	<b>16.3%</b>
Acute Myeloid Leukemia	1	1	0.5%	0.0%	0.6%	0.0%	3.3%
DCIS Left Breast	1	1	0.5%	0.0%	0.6%	0.0%	3.0%
Diffuse Metastatic disease to the bones	1	1	0.5%	0.0%	0.7%	0.0%	3.4%

	ICECURE (N= 194)			Kaplan-Meier**			
	Events†	Subjs‡	%°	Year 2	Year 5	Year 2 1-sided 95% CI UB	Year 5 1-sided 95% CI UB
Endometrial Cancer	2	2	1.0%	0.0%	1.2%	0.0%	3.8%
Hepatocellular carcinoma	1	1	0.5%	0.0%	0.7%	0.0%	3.5%
Kidney cancer	1	1	0.5%	0.0%	0.8%	0.0%	4.3%
Local recurrence	7	7	3.6%	0.0%	4.7%	0.0%	8.6%
Lung Adenocarcinoma	1	1	0.5%	0.5%	0.5%	2.8%	2.8%
Meningioma	1	1	0.5%	0.5%	0.5%	2.7%	2.7%
Metastatic breast cancer	1	1	0.5%	0.0%	0.7%	0.0%	3.6%
Non-small cell lung cancer	1	1	0.5%	0.5%	0.5%	2.8%	2.8%
Second primary BC	3	3	1.5%	0.0%	0.7%	0.0%	3.7%
<b>Nervous system disorders</b>	<b>12</b>	<b>12</b>	<b>6.2%</b>	<b>3.2%</b>	<b>6.9%</b>	<b>6.1%</b>	<b>10.9%</b>
Altered mental status	1	1	0.5%	0.0%	0.7%	0.0%	3.5%
Encephalopathy	1	1	0.5%	0.5%	0.5%	2.7%	2.7%
Intracranial hemorrhage	1	1	0.5%	0.5%	0.5%	2.7%	2.7%
Memory impairment	3	3	1.5%	0.5%	1.7%	2.7%	4.3%
Presyncope	1	1	0.5%	0.0%	0.6%	0.0%	3.0%
Stroke	2	2	1.0%	0.5%	1.2%	2.7%	3.9%
Syncope	1	1	0.5%	0.0%	0.7%	0.0%	3.5%
Thoracic stenosis	1	1	0.5%	0.6%	0.6%	2.9%	2.9%
Transient ischemic attacks	1	1	0.5%	0.6%	0.6%	2.8%	2.8%
<b>Renal and urinary disorders</b>	<b>4</b>	<b>4</b>	<b>2.1%</b>	<b>1.1%</b>	<b>2.4%</b>	<b>3.4%</b>	<b>5.5%</b>
Acute kidney injury	4	4	2.1%	1.1%	2.4%	3.4%	5.5%
<b>Respiratory, thoracic and mediastinal disorders</b>	<b>18</b>	<b>12</b>	<b>6.2%</b>	<b>3.2%</b>	<b>5.7%</b>	<b>6.1%</b>	<b>9.4%</b>
Aspiration	1	1	0.5%	0.5%	0.5%	2.8%	2.8%
COPD	1	1	0.5%	0.0%	0.0%	0.0%	0.0%
Dyspnea	5	2	1.0%	0.5%	1.2%	2.6%	3.9%
Emphysema	1	1	0.5%	0.5%	0.5%	2.8%	2.8%
Hypoxia	1	1	0.5%	0.5%	0.5%	2.8%	2.8%
Pleural effusion	4	4	2.1%	0.0%	1.3%	0.0%	4.0%
Pulmonary edema	1	1	0.5%	0.0%	0.6%	0.0%	3.1%
Respiratory failure	4	4	2.1%	1.6%	1.6%	4.0%	4.0%
<b>Vascular disorders</b>	<b>6</b>	<b>5</b>	<b>2.6%</b>	<b>1.6%</b>	<b>2.8%</b>	<b>4.1%</b>	<b>5.7%</b>
Bilateral Carotid Stenosis	1	1	0.5%	0.0%	0.6%	0.0%	3.2%
Hypertension	2	2	1.0%	0.0%	1.2%	0.0%	3.7%
Thromboembolic event	3	3	1.5%	1.6%	1.6%	4.1%	4.1%

† Total number of events without regard to length of follow-up.

‡ Number of subjects experiencing event without regard to length of follow-up.

° Percentage of subjects experiencing specific event without regard to length of follow-up.

\*\* Kaplan-Meier Estimates at day 365, 730, 1095, 1460, and 1825 with 1-sided 95% CI upper bound (UB).

Procedure relationship: Remotely, Possible, Probable, Unknown.

Adverse events with missing date are analyzed as relative day 1.

Source: Tables Safety\_FAS.sas; Analyzed: 09JUN2024

**Table 40: All Serious Adverse Events by AE Code and Timecourse - Primary Analysis Set**

	Days Post-Op										
	0	1-30	31-60	61-180	181-365	366-730	731-1095	1096-1460	1461-1825	>1825	Total
<b>All Events</b>	<b>0</b>	<b>1</b>	<b>3</b>	<b>7</b>	<b>12</b>	<b>14</b>	<b>23</b>	<b>25</b>	<b>29</b>	<b>13</b>	<b>127</b>
<b>Blood and lymphatic system disorders</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>2</b>	<b>0</b>	<b>4</b>
Anemia	0	0	0	0	0	0	0	0	1	0	1
Febrile Neutropenia	0	0	0	1	0	0	0	0	1	0	2
Leukocytosis	0	0	1	0	0	0	0	0	0	0	1
<b>Cardiac disorders</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>2</b>	<b>5</b>	<b>7</b>	<b>1</b>	<b>2</b>	<b>18</b>
Acute coronary syndrome	0	0	0	0	0	0	0	1	0	0	1
Aortic valve disease	0	0	0	0	0	0	1	0	0	0	1
Atrial fibrillation	0	0	0	0	0	0	1	0	0	1	2
Atrioventricular Block Complete	0	0	0	0	0	0	1	0	0	0	1
Cardiac arrest	0	0	0	0	0	0	1	1	0	0	2
Chest pain - cardiac	0	0	0	0	0	0	0	1	0	1	2
Heart failure	0	0	0	0	1	0	1	2	1	0	5
Myocardial infarction	0	0	0	0	0	1	0	1	0	0	2
Palpitations	0	0	0	0	0	1	0	0	0	0	1
Sick sinus syndrome	0	0	0	0	0	0	0	1	0	0	1
<b>Ear and labyrinth disorders</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>
Vestibular Disorder	0	0	0	1	0	0	0	0	0	0	1
<b>Gastrointestinal disorders</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>4</b>	<b>4</b>	<b>0</b>	<b>10</b>
Abdominal pain	0	0	0	0	0	0	0	1	0	0	1
Colitis	0	0	0	0	1	0	0	0	0	0	1
Constipation	0	0	1	0	0	0	0	0	1	0	2
Duodenal hemorrhage	0	0	0	0	0	0	0	1	0	0	1
Dysphagia	0	0	0	0	0	0	0	0	1	0	1
Obstruction gastric	0	0	0	0	0	0	0	2	0	0	2
Sigmoid diverticulitis	0	0	0	0	0	0	0	0	1	0	1
Small intestinal obstruction	0	0	0	0	0	0	0	0	1	0	1
<b>General disorders and administration site conditions</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>2</b>	<b>2</b>	<b>3</b>	<b>0</b>	<b>8</b>
COVID	0	0	0	0	0	0	0	1	2	0	3
Death NOS	0	0	0	0	0	0	2	1	0	0	3
Edema limbs	0	0	0	0	0	0	0	0	1	0	1
Multi-organ failure	0	0	0	0	0	1	0	0	0	0	1
<b>Infections and infestations</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>2</b>	<b>2</b>	<b>3</b>	<b>2</b>	<b>4</b>	<b>2</b>	<b>16</b>
Endocarditis infective	0	0	0	0	0	0	1	0	0	0	1
Lung infection	0	0	0	0	0	0	0	2	1	2	5
Sepsis	0	0	0	0	0	1	0	0	2	0	3
Skin infection	0	0	0	1	1	1	1	0	0	0	4
Upper respiratory infection	0	0	0	0	0	0	0	0	1	0	1

	Days Post-Op										
	0	1-30	31-60	61-180	181-365	366-730	731-1095	1096-1460	1461-1825	>1825	Total
Urinary tract infection	0	0	0	0	1	0	1	0	0	0	2
<b>Injury, poisoning and procedural complications</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>1</b>	<b>1</b>	<b>1</b>	<b>4</b>
Fall	0	0	0	0	0	0	0	0	1	1	2
Fracture	0	0	0	0	0	1	0	0	0	0	1
Hip fracture	0	0	0	0	0	0	0	1	0	0	1
<b>Metabolism and nutrition disorders</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>1</b>	<b>3</b>
Hypercalcemia	0	0	0	0	1	0	0	0	0	0	1
Hypokalemia	0	0	0	0	0	0	0	0	0	1	1
Malnutrition	0	0	0	0	0	0	0	1	0	0	1
<b>Musculoskeletal and connective tissue disorders</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>1</b>	<b>0</b>	<b>2</b>
Arthritis	0	0	0	0	0	0	0	0	1	0	1
Rhabdomyolysis	0	0	0	0	0	0	0	1	0	0	1
<b>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>1</b>	<b>1</b>	<b>5</b>	<b>4</b>	<b>7</b>	<b>2</b>	<b>21</b>
Acute Myeloid Leukemia	0	0	0	0	0	0	0	1	0	0	1
DCIS Left Breast	0	0	0	0	0	0	1	0	0	0	1
Diffuse Metastatic disease to the bones	0	0	0	0	0	0	0	1	0	0	1
Endometrial Cancer	0	0	0	0	0	0	2	0	0	0	2
Hepatocellular carcinoma	0	0	0	0	0	0	0	1	0	0	1
Kidney cancer	0	0	0	0	0	0	0	0	1	0	1
Local recurrence	0	0	0	0	0	0	2	1	4	0	7
Lung Adenocarcinoma	0	0	0	0	1	0	0	0	0	0	1
Meningioma	0	0	0	1	0	0	0	0	0	0	1
Metastatic breast cancer	0	0	0	0	0	0	0	0	1	0	1
Non-small cell lung cancer	0	0	0	0	0	1	0	0	0	0	1
Second primary BC	0	0	0	0	0	0	0	0	1	2	3
<b>Nervous system disorders</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>2</b>	<b>2</b>	<b>2</b>	<b>3</b>	<b>0</b>	<b>3</b>	<b>0</b>	<b>12</b>
Altered mental status	0	0	0	0	0	0	0	0	1	0	1
Encephalopathy	0	0	0	0	1	0	0	0	0	0	1
Intracranial hemorrhage	0	0	0	1	0	0	0	0	0	0	1
Memory impairment	0	0	0	0	1	0	2	0	0	0	3
Presyncope	0	0	0	0	0	0	1	0	0	0	1
Stroke	0	0	0	1	0	0	0	0	1	0	2
Syncope	0	0	0	0	0	0	0	0	1	0	1
Thoracic stenosis	0	0	0	0	0	1	0	0	0	0	1
Transient ischemic attacks	0	0	0	0	0	1	0	0	0	0	1
<b>Renal and urinary disorders</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>2</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>2</b>	<b>0</b>	<b>4</b>
Acute kidney injury	0	0	0	0	2	0	0	0	2	0	4

<b>Respiratory, thoracic and mediastinal disorders</b>	<b>0</b>	<b>1</b>	<b>1</b>	<b>0</b>	<b>1</b>	<b>4</b>	<b>2</b>	<b>3</b>	<b>1</b>	<b>5</b>	<b>18</b>
Aspiration	0	0	0	0	0	1	0	0	0	0	1
COPD	0	0	0	0	0	0	0	0	0	1	1
Dyspnea	0	1	0	0	0	0	0	2	1	1	5
Emphysema	0	0	0	0	0	1	0	0	0	0	1
Hypoxia	0	0	0	0	0	1	0	0	0	0	1
Pleural effusion	0	0	0	0	0	0	1	1	0	2	4
Pulmonary edema	0	0	0	0	0	0	1	0	0	0	1
Respiratory failure	0	0	1	0	1	1	0	0	0	1	4
<b>Vascular disorders</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>1</b>	<b>1</b>	<b>3</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>6</b>
Bilateral Carotid Stenosis	0	0	0	0	0	0	1	0	0	0	1
Hypertension	0	0	0	0	0	0	2	0	0	0	2
Thromboembolic event	0	0	0	1	1	1	0	0	0	0	3

Adverse events with missing date are analyzed as relative day 1.  
Source: Tables Safety by Severity-Timecourse\_FAS.sas; Analyzed: 09JUN2024

**Table 41: All Serious Adverse Events by Event Code and Severity**

	Mild		Moderate		Severe		Total
	Events	%*	Events	%*	Events	%*	Events
<b>All Events</b>	<b>5</b>	<b>3.9%</b>	<b>35</b>	<b>27.6%</b>	<b>87</b>	<b>68.5%</b>	<b>127</b>
<b>Blood and lymphatic system disorders</b>	<b>0</b>	<b>0.0%</b>	<b>1</b>	<b>25.0%</b>	<b>3</b>	<b>75.0%</b>	<b>4</b>
Anemia	0	0.0%	0	0.0%	1	100.0%	1
Febrile Neutropenia	0	0.0%	0	0.0%	2	100.0%	2
Leukocytosis	0	0.0%	1	100.0%	0	0.0%	1
<b>Cardiac disorders</b>	<b>2</b>	<b>11.1%</b>	<b>3</b>	<b>16.7%</b>	<b>13</b>	<b>72.2%</b>	<b>18</b>
Acute coronary syndrome	1	100.0%	0	0.0%	0	0.0%	1
Aortic valve disease	0	0.0%	0	0.0%	1	100.0%	1
Atrial fibrillation	0	0.0%	1	50.0%	1	50.0%	2
Atrioventricular Block Complete	0	0.0%	0	0.0%	1	100.0%	1
Cardiac arrest	0	0.0%	0	0.0%	2	100.0%	2
Chest pain - cardiac	0	0.0%	0	0.0%	2	100.0%	2
Heart failure	0	0.0%	2	40.0%	3	60.0%	5
Myocardial infarction	0	0.0%	0	0.0%	2	100.0%	2
Palpitations	1	100.0%	0	0.0%	0	0.0%	1
Sick sinus syndrome	0	0.0%	0	0.0%	1	100.0%	1
<b>Ear and labyrinth disorders</b>	<b>0</b>	<b>0.0%</b>	<b>1</b>	<b>100.0%</b>	<b>0</b>	<b>0.0%</b>	<b>1</b>
Vestibular Disorder	0	0.0%	1	100.0%	0	0.0%	1
<b>Gastrointestinal disorders</b>	<b>0</b>	<b>0.0%</b>	<b>3</b>	<b>30.0%</b>	<b>7</b>	<b>70.0%</b>	<b>10</b>
Abdominal pain	0	0.0%	0	0.0%	1	100.0%	1
Colitis	0	0.0%	0	0.0%	1	100.0%	1
Constipation	0	0.0%	0	0.0%	2	100.0%	2

	Mild		Moderate		Severe		Total
	Events	%*	Events	%*	Events	%*	Events
Duodenal hemorrhage	0	0.0%	1	100.0%	0	0.0%	1
Dysphagia	0	0.0%	0	0.0%	1	100.0%	1
Obstruction gastric	0	0.0%	0	0.0%	2	100.0%	2
Sigmoid diverticulitis	0	0.0%	1	100.0%	0	0.0%	1
Small intestinal obstruction	0	0.0%	1	100.0%	0	0.0%	1
<b>General disorders and administration site conditions</b>	<b>0</b>	<b>0.0%</b>	<b>1</b>	<b>12.5%</b>	<b>7</b>	<b>87.5%</b>	<b>8</b>
COVID	0	0.0%	1	33.3%	2	66.7%	3
Death NOS	0	0.0%	0	0.0%	3	100.0%	3
Edema limbs	0	0.0%	0	0.0%	1	100.0%	1
Multi-organ failure	0	0.0%	0	0.0%	1	100.0%	1
<b>Infections and infestations</b>	<b>1</b>	<b>6.3%</b>	<b>5</b>	<b>31.3%</b>	<b>10</b>	<b>62.5%</b>	<b>16</b>
Endocarditis infective	0	0.0%	0	0.0%	1	100.0%	1
Lung infection	1	20.0%	1	20.0%	3	60.0%	5
Sepsis	0	0.0%	0	0.0%	3	100.0%	3
Skin infection	0	0.0%	3	75.0%	1	25.0%	4
Upper respiratory infection	0	0.0%	1	100.0%	0	0.0%	1
Urinary tract infection	0	0.0%	0	0.0%	2	100.0%	2
<b>Injury, poisoning and procedural complications</b>	<b>0</b>	<b>0.0%</b>	<b>2</b>	<b>50.0%</b>	<b>2</b>	<b>50.0%</b>	<b>4</b>
Fall	0	0.0%	1	50.0%	1	50.0%	2
Fracture	0	0.0%	1	100.0%	0	0.0%	1
Hip fracture	0	0.0%	0	0.0%	1	100.0%	1
<b>Metabolism and nutrition disorders</b>	<b>0</b>	<b>0.0%</b>	<b>1</b>	<b>33.3%</b>	<b>2</b>	<b>66.7%</b>	<b>3</b>
Hypercalcemia	0	0.0%	0	0.0%	1	100.0%	1
Hypokalemia	0	0.0%	0	0.0%	1	100.0%	1
Malnutrition	0	0.0%	1	100.0%	0	0.0%	1
<b>Musculoskeletal and connective tissue disorders</b>	<b>1</b>	<b>50.0%</b>	<b>0</b>	<b>0.0%</b>	<b>1</b>	<b>50.0%</b>	<b>2</b>
Arthritis	0	0.0%	0	0.0%	1	100.0%	1
Rhabdomyolysis	1	100.0%	0	0.0%	0	0.0%	1
<b>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</b>	<b>0</b>	<b>0.0%</b>	<b>11</b>	<b>52.4%</b>	<b>10</b>	<b>47.6%</b>	<b>21</b>
Acute Myeloid Leukemia	0	0.0%	0	0.0%	1	100.0%	1
DCIS Left Breast	0	0.0%	0	0.0%	1	100.0%	1
Diffuse Metastatic disease to the bones	0	0.0%	0	0.0%	1	100.0%	1
Endometrial Cancer	0	0.0%	1	50.0%	1	50.0%	2
Hepatocellular carcinoma	0	0.0%	0	0.0%	1	100.0%	1
Kidney cancer	0	0.0%	0	0.0%	1	100.0%	1
Local recurrence	0	0.0%	7	100.0%	0	0.0%	7
Lung Adenocarcinoma	0	0.0%	1	100.0%	0	0.0%	1
Meningioma	0	0.0%	0	0.0%	1	100.0%	1
Metastatic breast cancer	0	0.0%	0	0.0%	1	100.0%	1
Non-small cell lung cancer	0	0.0%	0	0.0%	1	100.0%	1
Second primary BC	0	0.0%	2	66.7%	1	33.3%	3
<b>Nervous system disorders</b>	<b>1</b>	<b>8.3%</b>	<b>2</b>	<b>16.7%</b>	<b>9</b>	<b>75.0%</b>	<b>12</b>
Altered mental status	0	0.0%	0	0.0%	1	100.0%	1

	Mild		Moderate		Severe		Total
	Events	%*	Events	%*	Events	%*	Events
Encephalopathy	0	0.0%	0	0.0%	1	100.0%	1
Intracranial hemorrhage	0	0.0%	0	0.0%	1	100.0%	1
Memory impairment	1	33.3%	0	0.0%	2	66.7%	3
Presyncope	0	0.0%	1	100.0%	0	0.0%	1
Stroke	0	0.0%	1	50.0%	1	50.0%	2
Syncope	0	0.0%	0	0.0%	1	100.0%	1
Thoracic stenosis	0	0.0%	0	0.0%	1	100.0%	1
Transient ischemic attacks	0	0.0%	0	0.0%	1	100.0%	1
<b>Renal and urinary disorders</b>	<b>0</b>	<b>0.0%</b>	<b>1</b>	<b>25.0%</b>	<b>3</b>	<b>75.0%</b>	<b>4</b>
Acute kidney injury	0	0.0%	1	25.0%	3	75.0%	4
<b>Respiratory, thoracic and mediastinal disorders</b>	<b>0</b>	<b>0.0%</b>	<b>2</b>	<b>11.1%</b>	<b>16</b>	<b>88.9%</b>	<b>18</b>
Aspiration	0	0.0%	0	0.0%	1	100.0%	1
COPD	0	0.0%	0	0.0%	1	100.0%	1
Dyspnea	0	0.0%	0	0.0%	5	100.0%	5
Emphysema	0	0.0%	0	0.0%	1	100.0%	1
Hypoxia	0	0.0%	0	0.0%	1	100.0%	1
Pleural effusion	0	0.0%	2	50.0%	2	50.0%	4
Pulmonary edema	0	0.0%	0	0.0%	1	100.0%	1
Respiratory failure	0	0.0%	0	0.0%	4	100.0%	4
<b>Vascular disorders</b>	<b>0</b>	<b>0.0%</b>	<b>2</b>	<b>33.3%</b>	<b>4</b>	<b>66.7%</b>	<b>6</b>
Bilateral Carotid Stenosis	0	0.0%	1	100.0%	0	0.0%	1
Hypertension	0	0.0%	0	0.0%	2	100.0%	2
Thromboembolic event	0	0.0%	1	33.3%	2	66.7%	3

\*Percentage of total events.

Source: Tables Safety by Severity-Timecourse\_FAS.sas; Analyzed: 09JUN2024

**Table 42: All Serious Procedure Related Adverse Events by High and Low Terms – Primary Analysis Set**

	ICECURE (N= 194)			Kaplan-Meier**			
	Events†	Subjs‡	%°	Year 2	Year 5	Year 2 1-sided 95% CI UB	Year 5 1-sided 95% CI UB
<b>All Events</b>	<b>4</b>	<b>3</b>	<b>1.5%</b>	<b>0.0%</b>	<b>1.9%</b>	<b>0.0%</b>	<b>4.9%</b>
<b>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</b>	<b>4</b>	<b>3</b>	<b>1.5%</b>	<b>0.0%</b>	<b>1.9%</b>	<b>0.0%</b>	<b>4.9%</b>
Local recurrence	3	3	1.5%	0.0%	1.9%	0.0%	4.9%
Metastatic breast cancer	1	1	0.5%	0.0%	0.7%	0.0%	3.6%

† Total number of events without regard to length of follow-up.  
‡ Number of subjects experiencing event without regard to length of follow-up.  
° Percentage of subjects experiencing specific event without regard to length of follow-up.  
\*\* Kaplan-Meier Estimates at day 365, 730, 1095, 1460, and 1825 with 1-sided 95% CI upper bound (UB).  
Procedure relationship: Remotely, Possible, Probable, Unknown.  
Adverse events with missing date are analyzed as relative day 1.  
Source: Tables Safety\_FAS.sas; Analyzed: 09JUN2024

**Table 43: All Serious Procedure Related Adverse Events by AE Code and Timecourse – Primary Analysis Set**

	Days Post-Op										
	0	1-30	31-60	61-180	181-365	366-730	731-1095	1096-1460	1461-1825	>1825	Total
<b>All Events</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>2</b>	<b>0</b>	<b>2</b>	<b>0</b>	<b>4</b>
<b>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>2</b>	<b>0</b>	<b>2</b>	<b>0</b>	<b>4</b>
Local recurrence	0	0	0	0	0	0	2	0	1	0	3
Metastatic breast cancer	0	0	0	0	0	0	0	0	1	0	1

† Defined as Remotely/Possible/Probable and Unknown.  
Adverse events with missing date are analyzed as relative day 1.  
Source: Tables Safety by Severity-Timecourse\_FAS.sas; Analyzed: 09JUN2024

**Table 44: All Serious Procedure Related Adverse Events by AE Code and Severity - Primary Analysis Set**

	Mild		Moderate		Severe		Total
	Events	%*	Events	%*	Events	%*	Events
<b>All Events</b>	<b>0</b>	<b>0.0%</b>	<b>3</b>	<b>75.0%</b>	<b>1</b>	<b>25.0%</b>	<b>4</b>
<b>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</b>	<b>0</b>	<b>0.0%</b>	<b>3</b>	<b>75.0%</b>	<b>1</b>	<b>25.0%</b>	<b>4</b>
Local recurrence	0	0.0%	3	100.0%	0	0.0%	3
Metastatic breast cancer	0	0.0%	0	0.0%	1	100.0%	1

\*Percentage of total events. †Defined as Remotely/Possible/Probable and Unknown.  
Source: Tables Safety by Severity-Timecourse\_FAS.sas; Analyzed: 09JUN2024