

Brief Summary of the Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee

Meeting – May 17, 2017

Introduction

On May 17, 2017 the panel discussed, made recommendations and voted on information related to the premarket approval application for the TransMedics Organ Care System (OCS) Lung System sponsored by TransMedics, Inc. The TransMedics Organ Care System (OCS) Lung System is a portable organ perfusion, ventilation, and monitoring medical device intended to preserve donor lungs in a near physiologic, ventilated, and perfused state for transplantation.

Panel Deliberations

Effectiveness

The panel agreed that the long-term clinical outcomes (i.e., 2-year survival and bronchiolitis obliterans syndrome) in INSPIRE were comparable between the OCS Lung System and standard of care (cold static storage). Some panelists expressed concerns over the lower peri-operative survival of OCS subjects, especially out to 30 days. Incidence of ISHLT Primary Graft Dysfunction Grade 3 was comparable between the two study arms at T72 post-transplantation. The panelists agreed that the observed difference in rates of PGD 3 grading within 72 hours was driven by T0 gradings; most of the panel believed that PGD3 at T48 and T72 were more predicative of clinical outcomes than that at T0. Many panelists noted the slight increase in total preservation time and decrease in cold ischemia time as a benefit of the OCS Lung System. However, some panelists pointed out that the INSPIRE trial was not designed to evaluate donor lung utilization.

While acknowledging the complexity of the INSPIRE study, the majority of the panel expressed concerns over the trial conduct. Some panelists noted that the non-inferiority inference in the per protocol population (PP) was not robust due to apparent selection bias. Other panelists believed that imbalances in screen failures and protocol violations did not impact the interpretability of the study.

Safety

The majority of the panel believed the OCS Lung System to be safe System compared to standard of care, given that the number of serious lung graft-related adverse events up to 30 days following transplantation was similar in the two arms. A few panelists noted that safety was not adequately studied due the exclusion of subjects post-randomization.

Open Public Hearing

There were fifteen open public speakers including patients from the INSPIRE study, representatives from organ procurement organizations, and transplant surgeons. All but one speaker supported the use of the OCS Lung System.

Panel Vote Results

On question 1, the panelists voted eleven “Yes” to two “No” that there is reasonable assurance that the TransMedics Organ Care System (OCS) Lung System is safe for the proposed indications. There were no abstentions.

On question 2, the panelists voted eight “Yes” to five “No” that there is reasonable assurance that the TransMedics Organ Care System (OCS) Lung System is effective for the proposed indications. There were no abstentions.

On question 3, the panelists voted nine “Yes” to four “No” that the benefits of the TransMedics Organ Care System (OCS) Lung System outweigh the risks for the proposed indication. There were no abstentions

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