KERYX BIOPHARMACEUTICALS

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Dedicated to developing and commercializing novel therapies for the treatment of life-threatening diseases, including renal disease and cancer

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Corporate Overview

Keryx Biopharmaceuticals is focused on the acquisition, development and commercialization of medically important pharmaceutical products for the treatment of life-threatening diseases, including cancer and renal disease. Keryx is developing KRX-0401 (perifosine), a novel, potentially first-in-class, oral anti-cancer agent that inhibits Akt activation in the phosphoinositide 3-kinase (PI3K) pathway, and also affects a number of other key signal transduction pathways, including the JNK pathway, all of which are pathways associated with programmed cell death, cell growth, cell differentiation and cell survival. KRX-0401 has demonstrated both safety and clinical efficacy in several tumor types, both as a single agent and in combination with novel therapies. KRX-0401 is currently in Phase 3 clinical development for both refractory advanced colorectal cancer and multiple myeloma, and in Phase 1 and 2 clinical development for several other tumor types. Each of the KRX-0401 Phase 3 programs are being conducted under Special Protocol Assessment (SPA) agreements with the FDA. Keryx is also developing Zerenex™ (ferric citrate), an oral, iron-based compound that has the capacity to bind to phosphate and form non-absorbable complexes. The Phase 3 clinical program of Zerenex™ in the treatment for hyperphosphatemia (elevated phosphate levels) in patients with end-stage renal disease is being conducted pursuant to an SPA agreement with the FDA.

Keryx is headquartered in New York City.

Keryx Biopharmaceuticals is traded on the Nasdaq Stock Market under the symbol "KERX."

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Product Pipeline

Product candidate	Target indication	Development status
KRX-0401 (perifosine)	Multiple myeloma Colorectal cancer Multiple other forms of cancer	Phase 3 ongoing, under SPA Phase 3 ongoing, under SPA Phase 2 trials ongoing
Zerenex™ (ferric citrate)	Hyperphosphatemia in patients with end-stage renal disease	U.S. Phase 3 program ongoing under SPA; Japan Phase 3 program ongoing by sublicensee (JT and Torii)

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Product Pipeline

- Zerenex™
- KRX-0401 (Perifosine)

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Disclaimer: These investigational drug products have not been approved by the US Food and Drug Administration for safety and effectiveness. These investigational drug products are still undergoing clinical study to verify their safety and effectiveness

Product Pipeline

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  - Development Status
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About KRX-0401 (perifosine)

KRX-0401 (perifosine) is a novel, potentially first-in-class, oral anti-cancer agent that inhibits Akt activation in the phosphoinositide 3-kinase (PI3K) pathway, and also affects a number of other key signal transduction pathways, including the JNK pathway, all of which are pathways associated with programmed cell death, cell growth, cell differentiation and cell survival. The effects of KRX-0401 on Akt are of particular interest because of the importance of this pathway in the development of most cancers, with evidence that it is often activated in tumors that are resistant to other forms of anticancer therapy, and the difficulty encountered thus far in the discovery of drugs that will inhibit this pathway without causing excessive toxicity. High levels of activated Akt (pAkt) are seen frequently in many types of cancer and have been correlated with poor prognosis.

To date, over 2,000 patients have been treated with KRX-0401 in trials conducted both in the United States and Europe. Its safety profile is distinctly different from that of most cytotoxic agents. KRX-0401 does not appear to cause flu-like symptoms, thrombocytopenia (decrease in platelets that may result in bleeding) or alopecia (hair loss); all of these toxicities occur frequently with many of the currently available treatments for cancer. The main side effects of KRX-0401 are nausea, vomiting, diarrhea and fatigue, but these are generally well-managed particularly at lower daily doses (50 mg or 100 mg) that have induced tumor regression. Responses have been seen with both daily and weekly regimens. At the doses studied, the daily regimens were better tolerated.

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Clinical Trials KRX-0401

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Seven Phase 1 single agent studies of KRX-0401 have been completed; three in Europe by AEterna Zentaris Inc. and four in the United States by the NCI, a department of the National Institutes of Health, or NIH, as part of a Cooperative Research and Development Agreement, or CRADA, and by us. These trials demonstrated that KRX-0401 can be safely given to humans with a manageable toxicity profile. The dose limiting toxicity in the Phase 1 studies was gastrointestinal: nausea, vomiting and diarrhea. Additionally, we are conducting a Phase 1 study in the US which evaluates the safety of perifosine in pediatric patients.

Fourteen Phase 1/2 studies of KRX-0401 in combination with other drugs have been conducted by Keryx. Agents that have been included in these combinations include capecitabine (Xeloda®), gemcitabine, paclitaxel, docetaxel, prednisone, doxorubicin, pemetrexed, irinotecan, Doxil® (doxorubicin HCl liposome injection), trastuzumab, various endocrine therapies, imatinib, bortezomib, lenalidomide, sorafenib, and sunitinib. KRX-0401 has generally been well tolerated when used as a low daily dose (50 mg or 100 mg) in combination with these approved agents. KRX-0401 has also been studied in combination with radiotherapy without evidence of increased toxicity.

The NCI has completed a number of Phase 2 clinical trials studying KRX-0401 as a single agent, including studies in prostate, breast, head and neck and pancreatic cancers, as well as melanoma and sarcomas. In total, nine NCI clinical trials have been conducted across these six tumor types.

KRX-0401 has also been evaluated in eleven Phase 2 clinical studies conducted by Keryx evaluating the single agent activity in various tumor types where patients have progressed on standard treatments. Clinical trials where responses have been reported have been conducted in patients with renal cell carcinoma, advanced brain tumors, soft-tissue sarcomas, hepatocellular carcinoma, as well as in hematologic malignancies including multiple myeloma and Waldenstrom s macroglobulinemia. As illustrated in the previous NCI trials, the lower daily doses (50 mg or 100 mg) have been better tolerated than the intermittent higher doses.

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