Secura Bio Completes Acquisition of Global Rights to Oncology Drug Copiktra®

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Secura Bio, Inc. →
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LAS VEGAS, Sept. 30, 2020 /PRNewswire/ -- Secura Bio, Inc. (SBI) - (www.securabio.com), an integrated pharmaceutical company dedicated to the worldwide development and commercialization of impactful oncology therapies, today announced that it has completed the acquisition of the global rights to Copiktra® (duvelisib) for all oncology indications from Verastem, Inc.

Secura Bio's hematological oncology portfolio now includes Copiktra and Farydak® (panobinostat), an HDAC inhibitor.

Copiktra is an oral inhibitor of phosphoinositide 3-kinase (PI3K), and the first approved dual inhibitor of PI3K-delta and gamma involved in the signaling that leads to malignant B-cells proliferation and cancer.

Copiktra is indicated for the treatment of adult patients with relapsed or refractory chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) after at least two prior therapies and relapsed or refractory follicular lymphoma (FL) after at least two prior systemic therapies. Copiktra is also being developed for the treatment of peripheral T-cell lymphoma (PTCL), for which it has received Fast Track status and Orphan Drug Designation and is being investigated in combination with other agents through company and investigator-sponsored studies. A European Marketing Authorization Application for Copiktra was submitted in November 2019 to the European Medicines Agency (EMA) seeking approval for the treatment of patients with relapsed or refractory chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) and relapsed or refractory follicular lymphoma (FL).

Secura Bio will aggressively support the development of Copiktra in the treatment of T-cell lymphomas for which the PI3K inhibition-based mode of action is highly relevant, and explore new therapeutic opportunities for which the combination of PI3K and HDAC inhibitors (such as Secura Bio's other approved product - Farydak) may provide superior clinical outcomes.

"Completing the Copiktra acquisition represents a major step in building our worldwide oncology portfolio" said Joseph M. Limber, President and CEO of Secura Bio. "We are very excited about the near-term prospects for Copiktra in Peripheral T- cell lymphoma; the PRIMO study which is expected to complete dosing in the first half of 2021 may provide the substantive clinical data required for guidelines and potentially a label expansion. Copiktra compliments Farydak extremely well from both a commercial perspective and potentially a clinical perspective regarding opportunities in T- cell lymphomas. Secura Bio now has two meaningful oncology drugs with novel modes of action that provide the potential to build a very broad portfolio of indications in B-Cell and T-Cell lymphomas."

The transaction was partially financed with a $70 million debt and convertible debt financing led by Athyrium Capital Management, LP (www.athyrium.com), a leading healthcare focused investment firm, and the Secura Bio Executive Team.

About Secura Bio, Inc.

Secura Bio is an integrated, commercial-stage pharmaceutical company dedicated to the worldwide commercialization of significant oncology therapies for physicians and their patients. For more information on Secura Bio, please visit www.securabio.com

About Athyrium Capital Management

Athyrium is a specialized asset management company formed in 2008 to focus on investment opportunities in the global healthcare sector. Athyrium advises funds with over $3.7 billion in committed capital. The Athyrium team has substantial investment experience across a wide range of asset classes including public equity, private equity, fixed income, royalties, and other structured securities. Athyrium invests across all healthcare verticals including biopharma, medical devices and products, healthcare focused services, and healthcare information technology. The team partners with management teams to implement creative financing solutions to companies' capital needs.

About COPIKTRA (duvelisib)

COPIKTRA is an oral inhibitor of phosphoinositide 3-kinase (PI3K), and the first approved dual inhibitor of PI3K-delta and PI3K-gamma, two enzymes known to help support the growth and survival of malignant B-cells, in the United States. PI3K signaling may lead to the proliferation of malignant B-cells and is thought to play a role in the formation and maintenance of the supportive tumor microenvironment. COPIKTRA is indicated in the United States for the treatment of adult patients with relapsed or refractory chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) after at least two prior therapies and relapsed and has accelerated approval for refractory follicular lymphoma (FL) after at least two prior systemic therapies. COPIKTRA is also being developed by Verastem Oncology for the treatment of peripheral T-cell lymphoma (PTCL), for which it has received Fast Track status in the United States, and is being investigated in combination with other agents through investigator-sponsored studies. For more information on COPIKTRA, please visit www.COPIKTRA.com. Information about duvelisib clinical trials can be found on www.clinicaltrials.gov.

SELECT IMPORTANT SAFETY INFORMATION ABOUT COPIKTRA

This does not include all information needed to use COPIKTRA (duvelisib) safety and effectively. See full Prescribing Information.

WARNING: FATAL AND SERIOUS TOXICITIES: INFECTIONS, DIARRHEA OR COLITIS, CUTANEOUS REACTIONS, and PNEUMONITIS

See full Prescribing Information for complete boxed warning

- Fatal and/or serious infections occurred in 31% (4% fatal) of COPIKTRA-treated patients. Monitor for signs and symptoms of infection. Withhold COPIKTRA if infection is suspected.
- Fatal and/or serious diarrhea or colitis occurred in 18% (<1% fatal) of COPIKTRA-treated patients. Monitor for the development of severe diarrhea or colitis. Withhold COPIKTRA.
- Fatal and/or serious cutaneous reactions occurred in 5% (<1% fatal) of COPIKTRA-treated patients. Withhold COPIKTRA.
- Fatal and/or serious pneumonitis occurred in 5% (<1% fatal) of COPIKTRA-treated patients. Monitor for pulmonary symptoms and interstitial infiltrates. Withhold COPIKTRA.

INDICATIONS AND USAGE

COPIKTRA is a kinase inhibitor indicated for the treatment of adult patients with:

- Relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) after at least two prior therapies.
- Relapsed or refractory follicular lymphoma (FL) after at least two prior systemic therapies. Accelerated approval based on overall response rate and continued approval may be contingent upon confirmatory trials.

WARNINGS AND PRECAUTIONS

- Hepatotoxicity: Monitor hepatic function.
- Neutropenia: Monitor blood counts.
- Embryo-Fetal toxicity: COPIKTRA can cause fetal harm. Advise patients of potential risk to a fetus and to use effective contraception.

ADVERSE REACTIONS

The most common adverse reactions (≥20%) are diarrhea or colitis, neutropenia, rash, fatigue, pyrexia, cough, nausea, upper respiratory infection, pneumonia, musculoskeletal pain, and anemia.

To report Adverse Reactions, contact FDA at 1-800-FDA-1088 (1-800-332-1088) or www.fda.gov/medwatch and Verastem Oncology at 1-877-7RXVSTM (1-877-779-8786).

DRUG INTERACTIONS

- CYP3A inducers: Avoid co-administration with strong CYP3A inducers.
- CYP3A inhibitors: Monitor for COPIKTRA toxicities when co-administered with strong or moderate CYP3A inhibitors. Reduce COPIKTRA dose to 15 mg twice daily when co-administered with strong CYP3A4 inhibitors.
- CYP3A substrates: Monitor for signs of toxicities when co-administering COPIKTRA with sensitive CYP3A substrates.

USE IN SPECIFIC POPULATIONS

Lactation: Advise women not to breastfeed.

About Peripheral T-Cell Lymphoma

Peripheral T-cell lymphoma (PTCL) is a rare, aggressive type of non-Hodgkin lymphoma (NHL) that develops in mature white blood cells called "T cells" and "natural killer (NK) cells"[1] which circulate with the lymphatic system. PTCL accounts for between 10-15% of all non-Hodgkin lymphomas (NHLs) and generally affects people aged 60 years and older. Although there are many different subtypes of peripheral T-cell lymphoma, they often present in a similar way, with widespread, enlarged, painless lymph nodes in the neck, armpit or groin. There is currently no established standard of care for patients with relapsed or refractory disease.

SOURCE Secura Bio, Inc.

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