Burtomab Receives Breakthrough Therapy Designation for advanced form of pediatric cancer

June 7, 2017

Burtomab, a drug for metastatic neuroblastoma, has been granted Breakthrough Therapy Designation by the FDA for its treatment in pediatric patients with relapsed or refractory neuroblastoma with central nervous system or leptomeningeal metastasis.

NEW YORK, June 7, 2017-- Burtomab, a drug for metastatic neuroblastoma, created by Memorial Sloan Kettering Cancer Center (MSK) and licensed to YmAbs Therapeutics, Inc. (YmAbs), has been granted Breakthrough Therapy Designation by the FDA for its treatment in pediatric patients with relapsed or refractory neuroblastoma with central nervous system or leptomeningeal metastasis. MSK’s Nai-Kong Cheung, MD, PhD, created and tested the antibody that resulted in the breakthrough therapy designation.

Breakthrough Therapy Designation is a program intended to expedite the development and review of drugs to treat serious or life-threatening conditions when preliminary clinical evidence demonstrates that the drug may provide substantial improvement over available therapies. The Breakthrough Therapy Designation for burtomab was granted on the basis of data from a pivotal clinical study of burtomab with radiolabeled iodine (131I) for the treatment of neuroblastoma that metastasize to the central nervous system or the leptomeninges.

"Currently there are no approved drugs to treat this form of advanced neuroblastoma," says Dr. Cheung who has spent decades conducting pioneering research in developing treatments for neuroblastoma. "MSK takes every patient with neuroblastoma very seriously, and we are always looking for better ways to help this patient population. This development is an important step forward in our efforts to provide patients with new treatment options that may improve outcomes for children with this devastating disease."

YmAbs Founder, President and Head of Business Development and Strategy, Thomas Gad said, "We are very pleased that the FDA has granted the Breakthrough Therapy Designation to burtomab and thereby shortened the timeline for making this therapy available to the children having an urgent medical need. Burtomab clearly provides a potential curative treatment option for pediatric patients otherwise left with little or no options. This an important evidence advancement for YmAbs, and we are excited to work with our strategic partner MSK and the regulatory authorities to advance burtomab in patients suffering from neuroblastoma. From the outset, our goal has been to address neuroblastoma and other pediatric cancers with severe therapeutic needs in which there are few or no available therapeutic options."

Dr. Claus Møller, Chief Executive Officer, YmAbs says, "This is a major milestone for YmAbs and an important acknowledgement of the potential of burtomab to help patients with neuroblastoma that metastasize to the central nervous system or the leptomeninges."

About Breakthrough Therapy Designation:
The Breakthrough Therapy Designation was enacted as part of the 2012 FDA Safety and Innovation Act (FDASIA), which is intended to expedite development of drugs to treat serious and life-threatening medical conditions when preliminary clinical evidence demonstrates that the drug may provide substantial improvement over available therapies. Breakthrough Therapy Designation includes all the features of the Fast Track Designation, as well as more intensive guidance from the FDA on a drug’s clinical development program.

About YmAbs:
YmAbs is a clinical stage biopharmaceutical company focused on developing new cancer treatments through immunotherapies. By harnessing the power of the immune system to fight cancer, we aim to create innovative therapies that are safe, effective, and affordable. Our unique approach, which combines antibodies with radioisotopes, offers an alternative treatment option that can improve the quality of life for patients with advanced cancer. By targeting the tumor, our therapies reduce the toxicity seen with traditional chemotherapy and radiation, and allow for potentially less invasive treatment approaches in the future. We believe in the potential of radionuclide antibodies to help patients in need, even for patients with widespread disease. YmAbs’ goal is to drive multiple product candidates in select solid tumor cancers to FDA licensure. Each candidate has the potential to treat a variety of high-risk cancers.

To learn more, visit www.ymabs.com.

About Memorial Sloan Kettering:
We are the world’s oldest and largest private cancer center, home to more than 15,000 physicians, scientists, nurses, and staff united by a relentless dedication to conquering cancer. Our unparalleled accomplishments, continue 133 years of research and clinical leadership with the freedom to provide highly individualized, exceptional care to each patient. And our always growing educational programs continue to lead the field, here and around the world.

For more information, visit www.mskcc.org.

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