Burtomab Receives Breakthrough Therapy Designation for advanced form of pediatric cancer

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Burtomab, a drug for metastatic neuroblastoma, has been granted Breakthrough Therapy Designation by the FDA for the treatment of 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 Y-mAbs Therapeutics, Inc. (YmAbs), has been granted Breakthrough Therapy Designation by the FDA for the treatment of 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 diseases in cases where preliminary clinical evidence shows that the drug may provide substantial improvements over available therapy. 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 type of advanced neuroblastoma," says Dr. Cheung who has spent decades conducting pioneering research in developing treatments for neuroblastoma. "MSK treats more patients with neuroblastoma than any other institution in the world and with evidence-based treatment approaches like this we can offer real hope for better treatments to patients and families confronting 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 timelines for making this therapy available to the children facing an unmet medical need. Burtomab clearly provides a potential curative treatment option for pediatric patients otherwise faced with little or no options. This is an important milestone achievement for YmAbs, and we continue to work with our strategic partner MSK and the regulatory authorities to advance burtomab to patients suffering from Refractory Leptomeningeal Metastasis from Neuroblastoma as quickly as possible."

Dr. Claus Møller, Chief Executive Officer further notes, "This is the first time burtomab has earned the distinction of a Breakthrough Therapy Designation. We are pleased that the FDA continues to recognize 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) and is intended to expedite development of drugs to treat serious and life-threatening medical conditions when preliminary clinical evidence demonstrates that the drug may have substantial improvement on at least one clinically significant endpoint 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. In addition, YmAbs utilizes its platform technologies to create next-generation humanized, affinity matured bispecific antibodies targeting GD2 and B7H3. To further improve our bispecific antibodies, we are collaborating with MSK on the development of a novel human protein tag that dimerizes T-cell engaging bispecific antibodies, which enables higher tumor binding and results in a longer serum half-life and a significantly greater T-cell mediated killing of tumor cells. Our treatments could potentially reduce longer-term toxicities associated with current chemotherapeutics and provide the potential for curative therapy 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. As an independent institution, we combine 130 years of research and clinical leadership with the freedom to provide highly individualized, exceptional care to each patient. And our always-evolving educational programs continue to train new leaders in the field, here and around the world.

For more information, go to www.mskcc.org.

SOURCE:

Y-mAbs Therapeutics, Inc.

CONTACT:

Y-mabs Therapeutics, Inc.
750 Third Avenue, 9th Floor
New York, NY 10017
USA
+1 212 847 9844
E-mail: info@ymabs.com

Y-mAbs Therapeutics A/S
Rungsted Strandvej 113
2960 Rungsted Kyst
Denmark
+45 70 26 14 14
E-mail: info@ymabs.com