

Zumutor Biologics Inc announces FDA clearance of IND application of ZM008, a novel monoclonal antibody drug against multiple solid cancers

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Zumutor Biologics Inc "Zumutor", a Boston based biopharmaceutical company focused on developing unique novel therapeutics in immuno-oncology (I-O) today announces that the US Food and Drug Administration (FDA) has granted the company's Investigational New Drug (IND) application for the novel drug ZM008 to initiate a Phase 1, first-in-human, clinical study for the treatment of multiple solid cancers. ZM008 is a human IgG1 monoclonal antibody against LLT1 (CLEC2D), which disrupts the interaction of LLT1-CD161 between human immune cells and Tumor cells resulting in antitumor effects of ZM008 in monotherapy. The disruption of LLT1-CD161 interaction with ZM008 leads to reversal from "cold" or less immune responsive Tumor Microenvironment (TME) to "hot" highly immune responsive TME – the Holy Grail of I-O mechanisms.

FDA also accepted the "safety first" staggered parallel clinical design of ZM008 combination arm with Pembrolizumab to benefit a wider range of patients whose immune response could be boosted with ZM008 followed by Pembrolizumab treatment to obtain favourable disease responses.

"The U.S. Food and Drug Administration's approval of ZM008 IND application is an important milestone for Zumutor and a clear recognition of the intriguing preclinical data supporting novel/non overlapping mode of actions, generated thus far. Our work to translate the promise of Zumutor's INABLR[™] platform into improved and more potent human antibody products for patients in need will delve further into unique immune pathways involving NK cells and other innate immune compartments" said Dr Maloy Ghosh, PhD, Chief Scientific Officer, Zumutor Biologics. "We are now focusing on clinical execution of ZM008, closely working with oncologists for Phase I trial at NEXT Oncology, San Antonio and other sites in US, targeting first patient recruitment soon. We strongly believe this unique product will influence immune pathways involving both NK cell and T cell compartments with amazing potential for combination with Anti PD1 antibody like Pembrolizumab to benefit patients with advanced solid tumors".

"We believe that newer therapies like ZM008 will usher in options for patients and translate to better clinical outcomes. We anticipate start of Phase 1 studies in Q4 2023" said Kavitha lyer Rodrigues, Founder/ CEO of Zumutor

ZM008 Phase 1 study design will provide important information about the safety, tolerability, pharmacokinetics, pharmacodynamics, preliminary efficacy of monotherapy treatments as well as Recommended Phase 2 Dose (RP2D) of this novel drug in patients with solid cancers who are not benefited from existing 'standard of care'.



About ZM008:

ZM008 is a full length human IgG1 monoclonal antibody against LLT1 antigen on surface of various tumor cells. LLT1 - CD161 interaction leads to immune repressive condition in the TME allowing tumor cells to bypass the human immune system. ZM008 disrupts the LLT1-CD161 interaction and release the break from the immune cells – the activated immune cells then recognize and kill the tumor cells. The antitumor effects of ZM008 was demonstrated in elegant assays performed in humanized mice xenograft model and an *ex vivo* platform with biopsies from lung cancer and bladder cancer patients in presence of autologous PBMC.

About Zumutor Biologics

Zumutor is a novel immuno therapeutics company driving transformational change by harnessing the power of NK cells in modulating the Tumor Micro Environment (TME).

HQ'd in Boston, with labs in Bangalore, the company has developed a proprietary INABLR[™] platform consisting of multiple high diversity human antibody libraries which are mined through a combination of yeast and phage display technologies.

Zumutor's pipeline has two more assets targeting NK cell activation pathways involved in antitumor functions.

The company was founded in 2016 and has raised a total of 27Mil\$ from a strong syndicate of investors which include Accel Partners, Bharat Innovation Fund, Siana Capital, Aarin Capital, Chiratae, KITVEN.

To learn more, visit us at: www.zumutor.com

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