Jazz Pharmaceuticals and MD Anderson Announce Five-Year Collaboration to Evaluate Zanidatamab in HER2-Expressing Cancers

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DUBLIN and HOUSTON, Nov. 7, 2023 /PRNewswire/ -- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) and The University of Texas MD Anderson Cancer Center today announced a five-year strategic research collaboration agreement to evaluate zanidatamab, Jazz's investigational HER2-targeted bispecific antibody, in multiple HER2-expressing cancers.

The collaboration will combine MD Anderson's translational medicine and clinical research expertise with Jazz's expanding oncology drug development capabilities to investigate the potential of zanidatamab as monotherapy and in combination with other treatments for patients with different tumor types and stages. This includes its possible applicability in early-stage breast cancer, treatment areas where other HER2-directed therapies have failed, cancers with varying degrees of HER2-expression, and potentially rare, tissue-agnostic cancers.

"Current data indicates that zanidatamab has anti-tumor activity in multiple HER2-positive solid tumors, including positive results from a pivotal clinical trial for patients with HER2-amplified biliary tract cancers," said Funda Meric-Bernstam, M.D., chair of Investigational Cancer Therapeutics at MD Anderson. "We are pleased to extend our research efforts with Jazz through this new collaboration, which aims to address significant unmet needs in HER2-expressing solid tumors and to look for safe and effective alternatives to chemotherapy in diseases like early-stage breast cancer."

MD Anderson has been instrumental in researching breakthrough cancer therapies and was a key contributor to early investigations exploring the use of zanidatamab against an actionable target in the treatment of multiple tumor types and the subsequent Phase II HERIZON-BTC-01 trial, which evaluated zanidatamab for patients with treatment-refractory HER2-amplified biliary tract cancers. Results presented at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting demonstrated durable responses and a confirmed objective response rate of 41%. The presentation was selected for the 2023 Best of ASCO® program.

Jazz and MD Anderson will establish a joint steering committee to oversee the collaboration, which will fund multiple studies over its five-year term. Research under the collaboration is expected to begin in late 2023 or early 2024. This effort builds upon a previous strategic collaboration between Jazz and MD Anderson focused on hematologic malignancies.

"We think zanidatamab has best-in-class potential as a bispecific antibody utilizing biparatopic binding, which results in HER2 signal blockade, as well as immune-mediated cytotoxicity of HER2-expressing cancer cells. Zanidatamab has compelling anti-tumor activity across a broad range of HER2-positive cancers," said Rob Iannone, M.D., M.S.C.E., executive vice president, global head of research and development of Jazz Pharmaceuticals. "We look forward to continuing to collaborate with MD Anderson to further evaluate zanidatamab's potential to be transformative to the current standard-of-care in multiple HER2-expressing cancers. We are dedicated to advancing new treatment options for patients and we believe in the power of collaboration to accelerate the pace of research in difficult-to-treat cancers where persistent treatment gaps remain."

About Zanidatamab
Zanidatamab is an investigational bispecific antibody that can simultaneously bind two non-overlapping epitopes of HER2, known as biparatopic binding. This unique design results in multiple mechanisms of action including dual HER2 signal blockade, increased binding and removal of HER2 protein from the cell surface, and immune activation leading to encouraging antitumor activity in patients. Zanidatamab is being developed in multiple clinical trials as a targeted treatment option for patients with solid tumors that express HER2. Zanidatamab is being developed by Jazz and BeiGene, Ltd. (BeiGene) under license agreements from Zymeworks, which first developed the molecule.

The U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy designation for zanidatamab development in patients with previously treated HER2 gene-amplified biliary tract cancers (BTC), and two Fast Track designations for zanidatamab: one as a single agent for refractory BTC and one in combination with standard of care chemotherapy for first-line gastroesophageal adenocarcinoma (GEA). Additionally, zanidatamab has received Orphan Drug designations from FDA for the treatment of BTC and GEA, as well as Orphan Drug designation from the European Medicines Agency for the treatment of BTC and gastric cancer. Zanidatamab was also granted Breakthrough Therapy designation from the Center for Drug Evaluation (CDE) in China.

About MD Anderson
The University of Texas MD Anderson Cancer Center in Houston ranks as one of the world's most respected centers focused on cancer patient care, research, education and prevention. The institution's sole mission is to end cancer for patients and their families around the world, and, in 1971, it became one of the nation's first National Cancer Institute (NCI)-designated comprehensive cancer centers. MD Anderson is No. 1 for cancer in U.S. News & World Report's "Best Hospitals" rankings and has been named one of the nation's top two hospitals for cancer since the rankings began in 1990. MD Anderson receives a cancer center support grant from the NCI of the National Institutes of Health (P30 CA016672).

About Jazz Pharmaceuticals plc
Jazz Pharmaceuticals plc (Nasdaq: JAZZ) is a global biopharmaceutical company whose purpose is to innovate to transform the lives of patients and their families. We are dedicated to developing life-changing medicines for people with serious diseases—often with limited or no therapeutic options. We have a diverse portfolio of marketed medicines and novel product candidates, from early- to late-stage development, in neuroscience and oncology. Within these therapeutic areas, we are identifying new options for patients by actively exploring small molecules and biologics, and through innovative delivery technologies and cannabinoid science. Jazz is headquartered in Dublin, Ireland and has employees around the globe, serving patients in nearly 75 countries. Please visit www.jazzpharmaceuticals.com for more information.

Caution Concerning Forward-Looking Statements
This press release contains forward-looking statements, including, but not limited to, statements related to zanidatamab's best-in-class potential and potential to be transformative to the current standard-of-care in multiple HER2-expressing cancers and other statements that are not historical facts.

These forward-looking statements are based on Jazz Pharmaceuticals' current plans, objectives, estimates, expectations and intentions and inherently involve significant risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks and uncertainties associated with pharmaceutical product development, and other risks and uncertainties affecting Jazz Pharmaceuticals and its development programs, including those described from time to time under the caption "Risk Factors" and elsewhere in Jazz Pharmaceuticals plc's Securities and Exchange Commission filings and reports (Commission File No. 001-33500), including Jazz Pharmaceuticals' Annual Report on Form 10-K for the year ended December 31, 2022, as supplemented by our Quarterly Report on Form 10-Q for the quarter ended June 30, 2023, and future filings and reports by Jazz Pharmaceuticals. Other risks and uncertainties of which Jazz Pharmaceuticals is not currently aware may also affect Jazz Pharmaceuticals' forward-looking statements and may cause actual results and the timing of events to differ materially from those anticipated. The forward-looking statements herein are made only as of the date hereof or as of the dates indicated in the forward-looking statements, even if they are subsequently made available by Jazz Pharmaceuticals on its website or otherwise. Jazz Pharmaceuticals undertakes no obligation to update or supplement any forward-looking statements to reflect actual results, new information, future events, changes in its expectations or other circumstances that exist after the date as of which the forward-looking statements were made.

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