



Jazz Pharmaceuticals and Werewolf Therapeutics Announce Exclusive Global License and Collaboration Agreement to Develop WTX-613, a Differentiated, Conditionally-Activated IFN α INDUKINE™ Molecule

April 7, 2022

Werewolf to receive \$15 million upfront payment, with potential for up to \$1.26 billion in development, regulatory and sales milestone payments in addition to royalties on future net sales

WTX-613 expands Jazz's robust oncology pipeline and represents first immuno-oncology program in company's R&D portfolio

DUBLIN and CAMBRIDGE, Mass., April 7, 2022 /PRNewswire/ -- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) and Werewolf Therapeutics, Inc. (Nasdaq: HOWL) today announced that the companies have entered into a licensing agreement under which Jazz has acquired exclusive global development and commercialization rights to Werewolf's investigational WTX-613, a differentiated, conditionally-activated interferon alpha (IFN α) INDUKINE™ molecule.

"We believe WTX-613 has the potential to minimize the toxicity associated with systemic IFN α therapy, preferentially delivering IFN α to tumors, and thereby expanding its clinical utility in treating cancer. We are excited about the potential of WTX-613 based on compelling proof-of-concept data, recently presented at ASH, where a WTX-613 surrogate molecule demonstrated anti-tumor activity in preclinical models," said Rob Iannone, M.D., M.S.C.E., executive vice president, global head of research and development of Jazz Pharmaceuticals. "This transaction underscores our commitment to enhancing our pipeline to deliver novel oncology therapies to patients, and also provides us with an opportunity to expand into immuno-oncology. We will continue to identify and advance promising treatments and novel combinations as we aim to deliver at least five additional novel therapies to patients by the end of the decade as part of our Vision 2025."

WTX-613 is currently in preclinical development. Jazz expects to submit an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) for WTX-613 in 2023.

"We are thrilled to join forces with Jazz to advance WTX-613 on behalf of patients," said Daniel J. Hicklin, Ph.D., president and chief executive officer of Werewolf. "This partnership comes at an exciting time for Werewolf and enables WTX-613 to rapidly move toward the clinic, while we continue to advance our lead programs, WTX-124 and WTX-330, through expected IND filings this year."

WTX-613 is an engineered IFN α 2b cytokine pro-drug that is activated specifically within the tumor microenvironment where it can stimulate IFN α receptors on cancer-fighting immune effector cells. The aim of WTX-613 is to minimize the severe toxicities that have been observed with systemically active recombinant IFN α therapy and maximize clinical benefit when administered as monotherapy or in combination with other agents. Type 1 interferon signal transduction by IFN α agonism is a clinically validated mechanism of action, and IFN α has been shown to work synergistically in combination with other proven therapies including immune checkpoint inhibitors, targeted therapies and chemotherapy. This allows for potential application of WTX-613 across a wide range of cancer types, combination regimens and lines of therapy. WTX-613 was created leveraging Werewolf's proprietary PREDATOR™ protein engineering technology, which integrates specialized protein design elements to enhance activity, stability and tumor selectivity within a single molecule, called INDUKINE molecules.

At the American Society of Hematology (ASH) Annual Meeting in December 2021, Werewolf [presented data](#) from a surrogate WTX-613 INDUKINE molecule that demonstrated tumor stasis lasting beyond the treatment phase, efficiently blocked tumor growth, activated NK and CD8+ cell responses and induced antigen-presenting cell and effector cell markers in preclinical models.

Transaction Details

Under the terms of the transaction, Jazz has secured exclusive global rights to WTX-613. Jazz will make an upfront payment of \$15 million to Werewolf, and Werewolf is eligible to receive development, regulatory and commercial milestone payments of up to \$1.26 billion. Pending approval, Werewolf is eligible to receive a tiered, mid-single-digit percentage royalty on net sales of WTX-613.

About Jazz Pharmaceuticals

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. For more information, please visit www.jazzpharma.com and follow @JazzPharma on Twitter.

About Werewolf Therapeutics

Werewolf Therapeutics, Inc. is an innovative biopharmaceutical company pioneering the development of therapeutics engineered to stimulate the body's immune system for the treatment of cancer. We are leveraging our proprietary PREDATOR™ platform to design conditionally activated molecules that stimulate both adaptive and innate immunity with the goal of addressing the limitations of conventional proinflammatory immune therapies. Our INDUKINE™ molecules are intended to remain inactive in peripheral tissue yet activate selectively in the tumor microenvironment. Our most advanced product candidates, WTX-124 and WTX-330, are systemically delivered, conditionally activated Interleukin-2 (IL-2), and Interleukin-12 (IL-12) INDUKINE molecules, respectively, for the treatment of solid tumors. We are continuing preclinical studies for both WTX-124 and WTX-330 and expect to advance each candidate in multiple tumor types as a single agent and in combination with an immune checkpoint inhibitor. To learn more visit www.werewolfix.com.

Jazz Pharmaceuticals plc Caution Concerning Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements related to WTX-613's clinical utility in treating cancer; Jazz Pharmaceutical's goal to deliver at least five novel therapies to patients by the end of the decade; the potential successful submission of an investigational new drug application and future development, manufacturing, regulatory and commercialization activities; potential future payments by Jazz Pharmaceuticals to Werewolf Therapeutics for development, regulatory and commercial milestones as well as tiered royalties based on future net sales; 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: Jazz Pharmaceuticals' ability to achieve the expected benefits (commercial or otherwise) from the license agreement; pharmaceutical product development and clinical success thereof; the regulatory approval process; effectively commercializing any product candidates; and other risks and uncertainties affecting Jazz Pharmaceuticals, 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, 2021 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.

Werewolf Therapeutics, Inc. Caution Concerning Forward-Looking Statements

This press release contains forward-looking statements that involve substantial risk and uncertainties. All statements, other than statements of historical facts, contained in this press release, including statements regarding Werewolf's strategy, future operations, prospects, plans, objectives of management, WTX-613's clinical utility in treating cancer, the potential successful submission of an investigational new drug application and future development manufacturing, regulatory and commercial activities, and potential future payments by Jazz Pharmaceuticals to Werewolf for development, regulatory and commercial milestones, as well as tiered royalties for future net sales constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. The words "aim," "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "goal," "intend," "may," "might," "objective," "ongoing," "plan," "potential," "predict," "project," "should," "target," "will," or "would," or the negative of these terms, or other comparable terminology are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. The Company may not actually achieve the plans, intentions or expectations disclosed in these forward-looking statements, and you should not place undue reliance on these forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in these forward-looking statements as a result of various important factors, including: uncertainties inherent in the development of product candidates, including the conduct of research activities, the initiation and completion of preclinical studies and clinical trials; uncertainties as to the availability and timing of results from preclinical studies; the timing of and our ability to submit and obtain regulatory approval for investigational new drug applications; whether results from preclinical studies will be predictive of the results of later preclinical studies and clinical trials; the Company's ability to obtain sufficient cash resources to fund the Company's foreseeable and unforeseeable operating expenses and capital expenditure requirements; the impact of the COVID-19 pandemic on the Company's business and operations; as well as the risks and uncertainties identified in the "Risk Factors" section of the Company's Annual Report on Form 10-K for the year ended December 31, 2021, filed with the Securities and Exchange Commission ("SEC"), and in subsequent filings the Company may make with the SEC. In addition, the forward-looking statements included in this press release represent the Company's views as of the date of this press release. The Company anticipates that subsequent events and developments will cause its views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date of this press release.

Jazz Contacts

Investors:

Andrea N. Flynn, Ph.D.
Vice President, Head, Investor Relations
Jazz Pharmaceuticals plc
InvestorInfo@Jazzpharma.com
Ireland +353 1 634 3211
U.S. +1 650 496 2717

Media:

Kristin Bhavnani
Head of Global Corporate Communications
Jazz Pharmaceuticals plc
CorporateAffairsMediaInfo@Jazzpharma.com
Ireland +353 1 637 2141
U.S. +1 215 867 4948

Werewolf Contacts

Investors:

Jonathan M. Nugent
Stern IR
+1 212 698 8698
jonathan.nugent@sternir.com

Media:

Amanda Sellers
VERGE Scientific Communications
+1 301 332 5574

asellers@vergescientific.com

Company:

Ellen Lubman
Chief Business Officer
Werewolf Therapeutics
elubman@werewolftx.com



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