



Jazz Pharmaceuticals and ImmunoGen, Inc. Announce a Strategic Collaboration and Option Agreement to Develop and Commercialize Antibody-Drug Conjugate Products

August 29, 2017

Strengthens Jazz hematology/oncology portfolio with options for innovative development candidates IMGN779 and IMGN632

ImmunoGen to receive a \$75 million upfront payment, up to \$100 million in research support, a co-commercialization option, and potential future opt-in fees, milestones and royalties

ImmunoGen conference call to be held today at 8:00 AM EDT; Jazz conference call to be held today at 4:30 PM EDT

DUBLIN and WALTHAM, Mass., Aug. 29, 2017 /PRNewswire/ -- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) and ImmunoGen, Inc. (Nasdaq: IMGN) today announced that the companies have entered into a collaboration and option agreement granting Jazz Pharmaceuticals exclusive, worldwide rights to opt into development and commercialization of two early-stage, hematology-related antibody-drug conjugate (ADC) programs, as well as an additional program to be designated during the term of the agreement. The programs covered under the agreement include IMGN779, a CD33-targeted ADC for the treatment of acute myeloid leukemia (AML) in Phase 1 testing, and IMGN632, a CD123-targeted ADC for hematological malignancies expected to enter clinical testing before the end of the year.

Under the terms of the agreement, ImmunoGen will be responsible for the development of the three ADC programs prior to any potential opt-in by Jazz. Following any opt-in, Jazz would be responsible for any further development as well as for potential regulatory submissions and commercialization.

As part of the agreement, Jazz will pay ImmunoGen an upfront payment of \$75 million. Additionally, Jazz will pay ImmunoGen up to \$100 million in development funding over seven years to support the three ADC programs. For each program, Jazz may exercise its opt-in right at any time prior to a pivotal study or any time prior to a biologics license application (BLA) upon payment of an option exercise fee of mid-double digit millions or low triple digit millions, respectively. For each program to which Jazz elects to opt-in, ImmunoGen would be eligible to receive milestone payments based on receiving regulatory approval of the applicable product, plus tiered royalties as a percentage of commercial sales by Jazz, which depending upon sales levels and the stage of development at the time of opt-in, range from mid- to high single digits in the lowest tier to low 10's to low 20's in the highest tier. After opt-in, Jazz and ImmunoGen would share costs associated with developing and obtaining regulatory approvals of the applicable product in the United States (U.S.) and the European Union. ImmunoGen has the right to co-commercialize in the U.S. one product (or two products, under certain limited circumstances) with U.S. profit sharing in lieu of Jazz's payment of the U.S. milestone and royalties to ImmunoGen.

"We are pleased to enter into this collaboration with ImmunoGen, a well-known leader in the field of ADC technology, with demonstrated success in creating ADC molecules, including the only FDA-approved ADC product to treat metastatic breast cancer. This investment supports our long-term commitment to expand our hematology/oncology portfolio with the potential addition of multiple innovative antibody drug conjugates," said Bruce Cozadd, chairman and chief executive officer of Jazz Pharmaceuticals. "We look forward to the advancement of these ADC programs and the potential synergy of these compounds with our current products and pipeline, as new therapeutic options for cancer patients are urgently needed."

"This strategic partnership with Jazz significantly advances our goal of accelerating the development of our early-stage novel ADC assets. This deal joins us with a global partner, provides us with substantial funding to support these programs, and preserves the right to co-commercialize one of these assets," said Mark Enyedy, president and chief executive officer of ImmunoGen. "Jazz has demonstrated the ability to bring innovative compounds to patients and will make an ideal partner to help develop and commercialize our novel ADC assets targeting AML, and more broadly, in the area of hematology/oncology. In addition, this partnership significantly strengthens our financial position and moves us closer to delivering upon our mission of bringing ADC therapies to patients."

IMGN779 is a novel ADC that combines a high-affinity, humanized anti-CD33 antibody, a cleavable disulfide linker, and one of ImmunoGen's novel indolino-benzodiazepine payloads, called IGNs, which alkylate DNA without crosslinking, resulting in potent preclinical anti-leukemia activity with relative sparing of normal hematopoietic progenitor cells^{1,2}. IMGN779 is in Phase 1 clinical testing for the treatment of AML. IMGN632 is a preclinical stage humanized anti-CD123 antibody-based ADC that is a potential treatment for AML, blastic plasmacytoid dendritic cell neoplasm (BPDCN), myelodysplastic syndrome, B-cell acute lymphocytic leukemia, and other CD123-positive malignancies. IMGN632 uses a novel payload, linker, and antibody technology and in AML xenograft models has demonstrated a large therapeutic index³. ImmunoGen expects to file an investigational new drug application (IND) for IMGN632 this quarter and enroll the first patient in a Phase 1 study before the end of the year.

Jazz Pharmaceuticals Conference Call Details

Jazz Pharmaceuticals will host a conference call and live audio webcast today at 4:30 p.m. EDT/9:30 p.m. IST to discuss this transaction. Interested parties may access the live audio webcast and slide presentation via the Investors section of the Jazz Pharmaceuticals website at www.jazzpharmaceuticals.com. Please connect to the website prior to the start of the conference call to ensure adequate time for any software downloads that may be necessary to listen to the webcast. A replay of the webcast will be archived on the website for one week.

Jazz audio webcast/conference call:

U.S. Dial-In Number: +1 855 353 7924

International Dial-In Number: +1 503 343 6056

Passcode: 76457218

A replay of the conference call will be available through September 5, 2017 and accessible through one of the following telephone numbers, using the passcode below:

Replay U.S. Dial-In Number: +1 855 859 2056
Replay International Dial-In Number: +1 404 537 3406
Passcode: 76457218

ImmunoGen Conference Call Details

ImmunoGen will host a conference call and live audio webcast today at 8am EDT to discuss this transaction. Interested parties may access the live audio webcast via the Investors section of the ImmunoGen website at www.immunogen.com. A replay of the webcast will be archived on the website for approximately one week.

ImmunoGen audio webcast/conference call:

Dial-In Number: +1 719-457-2607
Passcode: 8332814

About Jazz Pharmaceuticals

Jazz Pharmaceuticals plc (Nasdaq: JAZZ) is an international biopharmaceutical company focused on improving patients' lives by identifying, developing and commercializing meaningful products that address unmet medical needs. The company has a diverse portfolio of products and product candidates, with a focus in the areas of sleep and hematology/oncology. In these areas, Jazz Pharmaceuticals markets Xyrem® (sodium oxybate) oral solution, Erwinaze® (asparaginase *Erwinia chrysanthemi*), Defitelio® (defibrotide sodium) and Vyxeos™ (daunorubicin and cytarabine) liposome for injection in the U.S. and markets Erwinaze® and Defitelio® (defibrotide) in countries outside the U.S. For more information, please visit www.jazzpharmaceuticals.com.

About ImmunoGen

ImmunoGen is a clinical-stage biotechnology company that develops targeted cancer therapeutics using its proprietary antibody-drug conjugate (ADC) technology. ImmunoGen's lead product candidate, mirvetuximab soravtansine, is in a Phase 3 trial for FRα-positive platinum-resistant ovarian cancer, and is in Phase 1b/2 testing in combination regimens for earlier-stage disease. ImmunoGen's ADC technology is used in Roche's marketed product, Kadcyla®, in other clinical-stage ImmunoGen product candidates, and in programs in development by Amgen, Bayer, Biotest, CytomX, Debiopharm, Lilly, Novartis, Sanofi and Takeda. More information about the Company can be found at www.immunogen.com.

Jazz Pharmaceuticals "Safe Harbor" Statement under the Private Securities Litigation Reform Act of 1995

This press release contains forward-looking statements, including, but not limited to, statements related to the potential exercise by Jazz Pharmaceuticals of its opt-in rights with respect to certain early-stage product candidates covered by the collaboration and option agreement, the potential benefits of such product candidates and related development and regulatory activities, potential future payments to ImmunoGen by Jazz Pharmaceuticals, the potential exercise by ImmunoGen of its co-commercialization rights with respect to such product candidates, Jazz Pharmaceuticals' commitment to expand its hematology/oncology portfolio with the potential addition of multiple innovative antibody drug conjugates, the advancement of the ADC program covered by the collaboration and option agreement and the potential synergy of these compounds with Jazz Pharmaceuticals' current products and pipeline, the timing of such events and activities, and other statements that are not historical facts. These forward-looking statements are based on the company's 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: whether Jazz Pharmaceuticals will exercise its opt-in rights with respect to certain early-stage product candidates covered by the collaboration and option agreement, and, if exercised, Jazz Pharmaceuticals' ability to achieve the expected benefits (commercial or otherwise) from the acquisition of rights to such product candidates; whether ImmunoGen will exercise its co-commercialization rights with respect to such product candidates; pharmaceutical product development and clinical success thereof; the regulatory approval process; and effectively commercializing any product candidates acquired by Jazz Pharmaceuticals under the collaboration and option agreement; and other risks and uncertainties affecting the company 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 the company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2017 and future filings and reports by the company. Other risks and uncertainties of which the company is not currently aware may also affect the company's 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 the company on its website or otherwise. The company 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.

ImmunoGen "Safe Harbor" Statement under the Private Securities Litigation Reform Act of 1995

This press release includes forward-looking statements. For these statements, ImmunoGen claims the protection of the safe harbor for forward-looking statements provided by the Private Securities Litigation Reform Act of 1995. It should be noted that there are risks and uncertainties related to the development of novel anticancer products, including IMG779 and IMG632, including risks relating to preclinical and clinical studies, their timing and results. A review of these risks can be found in ImmunoGen's Transition Report on Form 10-K for the six-month period ended December 31, 2016 and other reports filed with the Securities and Exchange Commission.

References:

- ¹ S. Adams et al, Abstract P526, Presented at the 22nd Congress of the European Hematology Association, June 22-25, 2017.
- ² Y. Kotvun et al. (2016) *Blood* 128:768.
- ³ S. Adams et al, Abstract 2832, Presented at the American Society of Hematology, December 3-6, 2016.



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SOURCE Jazz Pharmaceuticals plc

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