

Immunomedics

FDA GRANTS ACCELERATED APPROVAL FOR IMMUNOMEDICS' TRODELVY IN PREVIOUSLY-TREATED METASTATIC TRIPLE-NEGATIVE BREAST CANCER

First FDA-approved antibody-drug conjugate that targets the Trop-2 antigen

Trodelvy is the first antibody-drug conjugate approved by FDA specifically for the treatment of relapsed or refractory metastatic triple-negative breast cancer

Company to host conference call today at 5:00 p.m. Eastern Time

Morris Plains, N.J., April 22, 2020 --- [Immunomedics, Inc.](#) (NASDAQ: **IMMU**) ("Immunomedics" or the "Company"), a leading biopharmaceutical company in the area of antibody-drug conjugates (ADC), today announced that the U.S. Food and Drug Administration (FDA) has approved Trodelvy™ (sacituzumab govitecan-hziy) for the treatment of adult patients with metastatic triple-negative breast cancer (TNBC) who have received at least two prior therapies for metastatic disease. Trodelvy is the first ADC approved by the FDA specifically for relapsed or refractory metastatic TNBC and is also the first FDA-approved anti-Trop-2 ADC.¹

Trodelvy, which was granted Breakthrough Therapy Designation and Priority Review, was approved under the FDA's Accelerated Approval Program based on the objective response rate (ORR) and duration of response (DoR) observed in a single-arm, multicenter Phase 2 study. Continued approval may be contingent upon verification of clinical benefit in the confirmatory Phase 3 ASCENT study, which was recently halted by the independent Data Safety Monitoring Committee (DSMC) for compelling evidence of efficacy across multiple endpoints.

"The approval of Trodelvy, the first ADC approved specifically for metastatic TNBC, an aggressive cancer with a poor prognosis and few effective therapies, will give clinicians a novel tool for treating patients with this disease," stated Aditya Bardia, MD, MPH, Director of Precision Medicine at the Center for Breast Cancer, Massachusetts General Hospital Cancer Center and Assistant Professor of Medicine at Harvard Medical School. Dr. Bardia was the lead investigator of the Phase 2 study. "In our trial, Trodelvy demonstrated clinically meaningful responses in patients with difficult-to-treat metastatic TNBC and moves the needle towards better outcomes for patients with metastatic breast cancer."

In the single-arm Phase 2 study, Trodelvy demonstrated an ORR of 33.3 percent (95 percent CI: 24.6, 43.1) and a median DoR of 7.7 months (95 percent CI: 4.9, 10.8), as determined by local assessment, in 108 adult TNBC patients who had previously received a median of three prior systemic therapies in the metastatic setting (range: 2-10).¹

"We are proud to bring Trodelvy to patients with metastatic TNBC who are in dire need of new options. Trodelvy has the potential to become a standard of care in the management of TNBC, and we anxiously await the results of ongoing studies in other types of metastatic breast cancer," said Dr. Loretta M. Itri, Chief Medical Officer of Immunomedics. "This approval highlights the

potential of our unique ADC platform and strengthens the premise that the Trop-2 antigen found in many solid cancers is an important target for drug delivery. We are committed to broadening the potential use of Trodelvy in other Trop-2-expressing cancers, especially those with unmet need.”

Trodelvy carries a black box warning for severe neutropenia and severe diarrhea. The most common adverse reactions occurring in 25 or more percent of patients included nausea, neutropenia, diarrhea, fatigue, anemia, vomiting, alopecia, constipation, decreased appetite, rash and abdominal pain. The most common Grade 3 or 4 adverse events occurring in more than 5 percent of patients were neutropenia, white blood cell count decreased, anemia, hypophosphatemia, diarrhea, fatigue, nausea and vomiting. Two percent of patients discontinued treatment due to adverse events. There were no deaths related to treatment and no severe cases of neuropathy or interstitial lung disease.¹

“Trodelvy’s approval is a major milestone in our transformation from a research-based organization to a fully-integrated biopharmaceutical company, underscoring our commitment to bring innovative therapies to patients with hard-to-treat cancers,” said Dr. Behzad Aghazadeh, Executive Chairman of Immunomedics. “We are grateful to all of the patients, their families, physicians, and nurses who participated in our clinical trials and played a significant role in making this moment possible.”

The Company recently announced that the Phase 3 confirmatory ASCENT study of Trodelvy in metastatic TNBC, with over 500 patients enrolled, will be stopped early due to compelling efficacy across multiple endpoints, based on the unanimous recommendation of the DSMC. The Company remains on track to achieve topline results from the ASCENT study by mid-2020.

Conference Call

The Company will host a conference call and live audio webcast today at 5:00 p.m. Eastern Time to discuss the FDA approval. To access the conference call, please dial (877) 303-2523 or (253) 237-1755 using the Conference ID 4987526. The conference call will be webcast via the Investors page on the Company’s website at <https://immunomedics.com/investors/>. Approximately two hours following the live event, a webcast replay of the conference call will be available on the Company’s website for approximately 30 days.

About TRODELVY

Trodelvy (sacituzumab govitecan-hziy) is the lead product and the most advanced program in Immunomedics’ unique antibody-drug conjugate (ADC) platform. Trodelvy is an ADC that is directed against Trop-2, a cell-surface protein expressed in many solid cancers, making it an attractive target for Trodelvy to potentially address multiple types of cancer.² Trodelvy binds to Trop-2 and delivers the anti-cancer drug, SN-38, to kill cancer cells. Trodelvy is currently being evaluated as a treatment for eight hard-to-treat solid cancers.

About triple-negative breast cancer

Triple-negative breast cancer (TNBC) is an aggressive type of breast cancer, accounting for up to 20 percent of all breast cancers.³ TNBC is diagnosed more frequently in younger and premenopausal women and is highly prevalent in African American and Hispanic women.⁴ TNBC cells do not have estrogen or progesterone hormone receptors, or very much of the human epidermal growth factor receptor 2 – hence the term triple negative. This means that medicines that target these receptors are not typically effective in TNBC. There is currently no approved standard of care for people with previously-treated mTNBC.³

About Immunomedics

Immunomedics is a pioneering leader in next-generation antibody-drug conjugate (ADC) technology, committed to help transform the lives of people with hard-to-treat cancers. Our proprietary ADC platform centers on using a novel linker that does not require an enzyme to release the payload to deliver an active drug inside the tumor cell and the tumor microenvironment, thereby producing a bystander effect. TRODELVY, our lead ADC, is the first ADC FDA approved for the treatment of people with metastatic triple-negative breast cancer and is also the first FDA-approved anti-Trop-2 ADC. For additional information on the Company, please visit its website at <https://immunomedics.com/>. The information on its website does not, however, form a part of this press release.

Cautionary note regarding forward-looking statements

This release, in addition to historical information, may contain forward-looking statements made pursuant to the Private Securities Litigation Reform Act of 1995. Such statements, including statements regarding expectations for the timing of the commercial launch of TRODELVY and the Company's development of TRODELVY for additional indications, clinical trials (including the funding therefor, anticipated patient enrollment, trial outcomes, timing or associated costs), regulatory applications and related timelines, including the filing and approval timelines for BLAs and BLA supplements, out-licensing arrangements, forecasts of future operating results, potential collaborations, capital raising activities, and the timing for bringing any product candidate to market, involve significant risks and uncertainties and actual results could differ materially from those expressed or implied herein. Factors that could cause such differences include, but are not limited to, the Company's reliance on third-party relationships and outsourcing arrangements (for example in connection with manufacturing, logistics and distribution, and sales and marketing) over which it may not always have full control, including the failure of third parties on which the Company is dependent to meet the Company's business and operational needs for investigational or commercial products and, or to comply with the Company's agreements or laws and regulations that impact the Company's business; the Company's ability to meet post-approval compliance obligations (on topics including but not limited to product quality, product distribution and supply chain requirements, and promotional and marketing compliance); imposition of significant post-approval regulatory requirements on our product candidates, including a requirement for a post-

approval confirmatory clinical study, or failure to maintain or obtain full regulatory approval for the Company's product candidates, if received, due to a failure to satisfy post-approval regulatory requirements, such as the submission of sufficient data from a confirmatory clinical study; the uncertainties inherent in research and development; safety and efficacy concerns related to the Company's products and product candidates; uncertainties in the rate and degree of market acceptance of products and product candidates, if approved; inability to create an effective direct sales and marketing infrastructure or to partner with third parties that offer such an infrastructure for distribution of the Company's product candidates, if approved; inaccuracies in the Company's estimates of the size of the potential markets for the Company's product candidates or limitations by regulators on the proposed treatment population for the Company's products and product candidates; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of the Company's products and product candidates; the Company's dependence on business collaborations or availability of required financing from capital markets, or other sources on acceptable terms, if at all, in order to further develop our products and finance our operations; new product development (including clinical trials outcome and regulatory requirements/actions); the risk that we or any of our collaborators may be unable to secure regulatory approval of and market our drug candidates; risks relating to the COVID-19 pandemic in the U.S. and around the world; risks associated with litigation to which the Company is or may become a party, including the cost and potential reputational damage resulting from such litigation; loss of key personnel; competitive risks to marketed products; and the Company's ability to repay its outstanding indebtedness, if and when required, as well as the risks discussed in the Company's filings with the Securities and Exchange Commission. The Company is not under any obligation, and the Company expressly disclaims any obligation, to update or alter any forward-looking statements, whether as a result of new information, future events or otherwise.

References

1. TRODELVY Prescribing Information. Morris Plains, NJ: Immunomedics Inc, 2020.
2. Fenn KM and Kalinsky K. Sacituzumab govitecan: antibody-drug conjugate in triple-negative breast cancer and other solid tumors. *Drugs of Today* 2019, 55(9):575-585.
3. Li CH, Karantza V, Aktan G, et al. Current treatment landscape for patients with locally recurrent inoperable or metastatic triple-negative breast cancer: a systematic literature review. *Breast Cancer Res.* 2019 Dec 16;21(1):143.
4. Wahba HA, El-Hadaad HA. Current approaches in treatment of triple-negative breast cancer. *Cancer Biol Med.* 2015 Jun;12(2):106-16.

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