



Idera Pharmaceuticals Announces New U.S. Patent Coverage for Tilsotolimod Through September 2037

September 28, 2020 12:45 PM EDT

– Protects Method-of-Use in CRC and HNSCC –

EXTON, Pa., Sept. 28, 2020 (GLOBE NEWSWIRE) -- Idera Pharmaceuticals, Inc. (Nasdaq: IDRA) today announced that the U.S. Patent and Trademark Office has issued U.S. Patent No. 10,772,907 (the '907 Patent) and allowed U.S. Patent Application No. 16/557,597 (the '597 Application), both entitled "Immune Modulation with TLR9 Agonists for Cancer Treatment" and each of which includes the Company's investigational therapy tilsotolimod.

The new patent and allowed application each include 26 claims directed to methods of treating colorectal cancer (CRC) (the '907 Patent) and head and neck squamous cell carcinoma (HNSCC) (the '597 Application) with intratumoral administration of tilsotolimod in combination with certain immune checkpoint inhibitor therapies, including CTLA-4, PD-1 or PD-L1 proteins. This new coverage expands protection of the first tilsotolimod method-of-use patent, which was directed to methods of treating metastatic melanoma and was issued in November 2019. The patents and the allowed application provide exclusivity for certain uses of tilsotolimod through September 2037.

"The CRC patent and the soon-to-issue HNSCC patent fortify our 'beyond melanoma' strategy for tilsotolimod, which currently includes ongoing development in MSS-CRC via our ILLUMINATE-206 trial and in HNSCC via our collaboration with AbbVie," said Vincent Milano, Idera's Chief Executive Officer. "These additional new intellectual property protections also demonstrate our commitment to tilsotolimod and to furthering its development potentially to address unmet need for patients living with cancer."

About MSS-CRC and ILLUMINATE-206

Colorectal cancer involves the abnormal growth of cells in the colon or rectum. This type of cancer is typically tested to determine its "MSI" status, which will inform treatment approach and prognosis. MSI stands for "microsatellite instable." MSI-High (MSI-H) means that there is a high amount of instability in a tumor, whereas MSS tumors are "microsatellite stable." According to the American Cancer Society and other references, annually in the United States, approximately 140,000 people are diagnosed with CRC, of which 85% are MSS, and approximately 50,000 deaths are attributed to CRC.

MSS-CRC has been shown to be highly immunosuppressive; there are no approved immunotherapy options. Given tilsotolimod's mechanism of action of activating dendritic cells, it may serve a complementary function to Yervoy® and Opdivo® within the immunosuppressive tumor microenvironment of MSS-CRC patients.

ILLUMINATE-206 is a Phase 2, open-label, multi-center study to evaluate tilsotolimod in combination with Opdivo® and Yervoy®* in immunotherapy-naïve micro-satellite stable colorectal cancer (MSS-CRC) patients. For more information on this trial, please visit [ClinicalTrials.gov](https://clinicaltrials.gov).

About HNSCC and the AbbVie Collaboration

Head and neck squamous cell carcinoma (HNSCC) develop in the flat, scale-like cells that form the lining of the mouth, nose, and throat. If HNSCC metastasizes to other parts of the body, such as the lymph nodes or lungs, the cancer has a worse prognosis and can be fatal. HNSCC is the seventh most common cancer worldwide. Each year, approximately 50,000 new cases are diagnosed and approximately 11,000 deaths are attributed to HNSCC in the United States.

In patients with relapsed or metastatic HNSCC, an overall survival benefit has been demonstrated for anti-PD-1 immune therapies versus standard of care chemotherapy. The challenge remains to increase the percentage of patients responding to these treatments, which currently ranges from 13% to 23%, depending on the line of therapy. Given tilsotolimod's mechanism of action of activating dendritic cells, it may serve a complementary function to immune therapies within the tumor microenvironment of HNSCC patients.

For more information regarding Idera's collaboration with AbbVie in HNSCC, see Idera's September 2019 [press release](#) or visit [ClinicalTrials.gov](https://clinicaltrials.gov).

About Tilsotolimod (IMO-2125)

Tilsotolimod is an investigational, synthetic Toll-like receptor 9 agonist. Intratumoral injection of tilsotolimod has been shown to promote both innate and adaptive immune activation. Tumors with an active immune response appear to respond better to CPIs than those that exclude or inhibit anti-tumor immune cells. Tilsotolimod in combination with CPIs may cause regression of locally injected and distant tumor lesions and increase the number of patients who benefit from immunotherapy. Tilsotolimod has received both Fast Track designation and Orphan Drug designation from the FDA and is being evaluated in multiple tumor types and in combination with multiple checkpoint and costimulation therapies. For more information on tilsotolimod trials, please visit [ClinicalTrials.gov](https://clinicaltrials.gov).

About Idera Pharmaceuticals

Harnessing the approach of the earliest researchers in immunotherapy and the company's vast experience in developing proprietary immunology platforms, Idera's development program is focused on priming the immune system to play a more powerful role in fighting cancer, ultimately increasing the number of people who can benefit from immunotherapy. Idera also continues to focus on the acquisition, development, and ultimate commercialization of drug candidates for both oncology and rare disease indications characterized by small, well-defined patient populations with serious unmet needs. To learn more about Idera, visit iderapharma.com.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements, other than statements of historical fact, included or incorporated in this press release, including statements regarding the Company's strategy, future operations, collaborations, intellectual property, cash resources, financial position, future revenues, projected costs, prospects, clinical trials, plans, and objectives of management, are forward-looking statements. The words "believes," "anticipates," "estimates," "plans," "expects," "intends," "may," "could," "should," "potential," "likely," "projects," "continue," "will," and "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these

identifying words. Idera cannot guarantee that it will achieve the plans, intentions or expectations disclosed in its forward-looking statements and you should not place undue reliance on the Company's forward-looking statements. There are several important factors that could cause Idera's actual results to differ materially from those indicated or implied by its forward-looking statements. Factors that may cause such a difference include: whether the Company's cash resources will be sufficient to fund the Company's continuing operations and the further development of the Company's programs for the period anticipated; whether interim results from a clinical trial, such as the preliminary results reported in this release, will be predictive of the final results of the trial; whether results obtained in preclinical studies and clinical trials such as the results described in this release will be indicative of the results that will be generated in future clinical trials, including in clinical trials in different disease indications; whether products based on Idera's technology will advance into or through the clinical trial process when anticipated or at all or warrant submission for regulatory approval; whether such products will receive approval from the U.S. Food and Drug Administration or equivalent foreign regulatory agencies; whether, if the Company's products receive approval, they will be successfully distributed and marketed; whether the Company's collaborations will be successful; and such other important factors as are set forth under the caption "Risk factors" in the Company's Annual Report filed on Form 10-K for the period ended December 31, 2017 and the Company's Quarterly Report filed on Form 10-Q for the period ended September 30, 2018. Although Idera may elect to do so at some point in the future, the Company does not assume any obligation to update any forward-looking statements and it disclaims any intention or obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

*Yervoy (ipilimumab) and Opdivo (nivolumab) are registered trademarks of Bristol Myers Squibb.

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Source: Idera Pharmaceuticals, Inc.