Outlook Therapeutics, Inc. Logo

Outlook Therapeutics Signs Manufacturing Supply Agreement with FUJIFILM Diosynth Biotechnologies as Part of Commercialization Strategy for ONS-5010

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CRANBURY, N.J., June 03, 2019 (GLOBE NEWSWIRE) -- Outlook Therapeutics, Inc. (NASDAQ: OTLK) (the "Company"), a late clinical-stage biopharmaceutical company focused on developing ONS-5010, a proprietary ophthalmic bevacizumab product candidate for the treatment of wet age related macular degeneration (wet AMD) and other retinal diseases, today announced that it has signed a master services agreement with FUJIFILM Diosynth Biotechnologies (FDB) for the production of ONS-5010. Under the terms of this agreement, FDB will provide global manufacturing of ONS-5010 to Outlook in support of the commercialization strategy for the drug. Additional terms of the agreement were not disclosed.

"Our master services agreement with FDB secures a world class manufacturing facility for the potential commercial launch of ONS-5010. Most importantly, FDB has the ability to rapidly scale manufacturing of ONS-5010 while maintaining the quality controls that meet or exceed regulatory requirements," said Terry Dagnon, Chief Operating Officer at Outlook Therapeutics, Inc. "Identifying a highly-regarded manufacturing partner for ONS-5010 is an important part of our commercialization strategy and is a required part of the Biologics License Application, or BLA, submission in wet AMD."

FDB is focused on combining technical leadership in cell culture, microbial fermentation and viral vectors with world class GMP manufacturing facilities to advance tomorrow's medicines. For over 25 years they have been supporting customers with the development and manufacture of recombinant proteins, viral vaccines and gene therapies.

"We are pleased that Outlook Therapeutics has selected FUJIFILM Diosynth Biotechnologies to partner in the commercial development of ONS-5010," said Gerry Fareell, Chief Operating Officer Texas, at FDB. "ONS-5010 is an important development in the treatment of wet AMD and we are excited to be a part of the program."

Lawrence A. Kenyon, President, Chief Executive Officer and Chief Financial Officer at Outlook Therapeutics, Inc., stated, "We continue to make steady progress across several fronts as we advance our ONS-5010 program in wet AMD. This new partnership with FDB is a critical next step as ONS-5010 advances through Phase 3 clinical trials towards a BLA submission we are planning for late 2020."

Outlook Therapeutics is currently conducting two Phase 3 clinical studies for ONS-5010. If successful, these studies will support the Company's plan to submit for regulatory approval in multiple markets in 2020. ONS-5010, if approved, has potential to mitigate risks associated with off-label use of Avastin or other drugs. Off-label use of Avastin is currently estimated to account for at least 50% of all wet AMD prescriptions in the United States.

About ONS-5010
ONS-5010 is a proprietary ophthalmic formulation of bevacizumab to be administered as an intravitreal injection for the treatment of wet AMD and other retina diseases. Bevacizumab is a full length humanized anti-VEGF (Vascular Endothelial Growth Factor) antibody that inhibits VEGF and associated angiogenic activity. The Company's proprietary ophthalmic bevacizumab product candidate is an anti-VEGF recombinant humanized monoclonal antibody (or mAb) formulated as a single use vial for IVT injection. By inhibiting the VEGF receptor from binding, bevacizumab prevents the growth and maintenance of tumor blood vessels.

About FUJIFILM Diosynth Biotechnologies
FUJIFILM Diosynth Biotechnologies is an industry-leading Biologics Contract Development and Manufacturing Organization (CDMO) with locations in Billingham and Redcar, UK, RTP, North Carolina and College Station, Texas. FUJIFILM Diosynth has over twenty five years of experience in the development and manufacturing of recombinant proteins, vaccines, monoclonal antibodies, among other large molecules, viral products and medical countermeasures expressed in a wide array of microbial, mammalian, and host/virus systems. The company offers a comprehensive list of services from cell line development using its proprietary pAVEway™ microbial and Apollo™ cell line systems to process development, analytical development, clinical and FDA-approved commercial manufacturing. FUJIFILM Diosynth Biotechnologies is a partnership between FUJIFILM Corporation and Mitsubishi Corporation. For more information, go to: www.fujifilmdiosynth.com

About Outlook Therapeutics, Inc.
Outlook Therapeutics is a clinical-stage biopharmaceutical company focused on developing its lead clinical program, ONS-5010, a proprietary ophthalmic bevacizumab product candidate for the treatment of wet age related macular degeneration (wet AMD) and other retina diseases. ONS-5010 is currently in Phase 3 clinical trials for patients suffering from wet AMD. For more information, please visit www.outlooktherapeutics.com.

Forward-Looking Statements
This press release contains forward-looking statements. All statements other than statements of historical facts are "forward-looking statements," including those relating to future events. In some cases, you can identify forward-looking statements by terminology such as "may," "might," "will," "should," "expect," "plan," "anticipate," "project," "believe," "estimate," "predict," "potential," "intend" or "continue," the negative of terms like these or other comparable terminology, and other words or terms of similar meaning. These include statements about the Company's engagement of FDB as global manufacturer, FDB's ability to rapidly scale manufacturing, the Company's clinical trials and plans for seeking regulatory approval for ONS-5010, its commercialization of ONS-5010 and the ability of ONS-5010 to mitigate risks associated with off-label use of Avastin, among others. Although the Company believes that it has a reasonable basis for forward-looking statements contained herein, they are based on current expectations about future events affecting the Company and are subject to risks, uncertainties and factors relating to its operations and business environment, all of which are difficult to predict and many of which are beyond its control. These risk factors include those risks associated with developing pharmaceutical product candidates, risks of conducting clinical trials, and risks in obtaining necessary regulatory approvals, and the risks of commercial manufacturing of pharmaceutical products, as well as those risks detailed in the Company's filings with the Securities and Exchange Commission. These risks may cause actual results to differ materially from those expressed or implied by forward-looking statements in this press release. All forward-looking statements included in this press release are expressly qualified in their entirety by the foregoing cautionary statements. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. The Company does not undertake any obligation to update, amend or clarify these forward-looking statements whether as a result of new information, future events or otherwise, except as may be required under applicable securities law.

For additional details on the Company's financial performance during the quarter, please see the Company's filings with the Securities and Exchange Commission.

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