May 17, 2018
BrightPath Biotherapeutics, Co., Ltd.

Announcement on the Results of the Phase III Clinical Trial for Cancer Peptide Vaccine ITK-1 in Patients in Japan with Prostate Cancer

Tokyo, May 17, 2018 — BrightPath Biotherapeutics ("BrightPath"), a biopharmaceutical company, announces that the recent unblinding* of the phase III double-blind, placebo-controlled study for ITK-1, a cancer peptide vaccine licensed by us to FUJIFILM Corporation ("FUJIFILM), in patients with prostate cancer that has been conducted by us on contract for FUJIFILM (hereinafter the "Double-Blind Trial"), has revealed non-achievement of the primary endpoint.

The recent Double-Blind Trial was conducted with the intention of determining the efficacy and safety of ITK-1 in patients with HLA-A24 positive, castration-resistant, docetaxel-resistant prostate cancer compared to a placebo group. The results showed no statistically significant improvement in the ITK-1-treated group in terms of overall survival (OS), which was the primary endpoint, compared to the placebo group. Overall analyses of adverse reactions to ITK-1 showed that ITK-1 was safe and well-tolerated.

Future policy will be discussed by licensee FUJIFILM based on a detailed analysis of the clinical trial data.

The potential impact of these results on our performance for the fiscal year ending March 31, 2019 is currently under close consideration. If we conclude that our earnings estimates announced on May 11, 2018 need to be revised, we will make a prompt announcement.

[Glossary]
*Unblinding: In a double-blind trial, neither the physician who administers the drug nor the patient knows whether the drug being administered is the investigational drug or the placebo. After the completion of data lock, whether the patient was assigned to the treatment group or the placebo group is disclosed. This is called "unblinding" or "breaking the blind." After all clinical trial data has been collected and the data lock completed, the results of the placebo-controlled trial are revealed by disclosing information on which patients were assigned to investigational drug or the placebo.

Contact

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