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To Whom It May Concern

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Commences in Domestic Patients Administration of VB-111, a gene therapy product
Global Phase III Trial in Platinum-Resistant Ovarian Cancer

Recently, we began the first administration of VB-111 in Japan as part of a joint, global phase III trial involving platinum-resistant ovarian cancer patients (OVAL study). VB-111 is a gene therapy product and we have acquired exclusive domestic development and marketing rights to the product from the Israel company VBL Therapeutics (VBL).

We are planning to administer the drug to 30 patients at 12 institutions in Japan.

Patient enrollment has begun at:	National Defense Medical College Hospital
	National Cancer Center Central Hospital
	Niigata Cancer Center
	Ehime University Hospital
	Hokkaido University Hospital
	Cancer Institute Hospital of JFCR
	National Cancer Center Hospital East
Being prepared	Five other institutions

The OVAL study is global trial, and patients are smoothly being enrolled overseas. More than 260 patients have already been enrolled. The design of the study calls for the enrollment of a total of 400 patients including the patients in Japan.

The clinical trial amendment included a second, separate primary endpoint, of progression free survival (PFS), in addition to the original primary endpoint of the trial, overall survival (OS). Based upon the changes that were reviewed by the U.S. Food and Drug Administration (FDA), successfully meeting either primary endpoint is expected to be sufficient to support a Biologic License Applications (BLA) submission. Successful meeting of the PFS endpoint, with a readout anticipated in 2022, could accelerate BLA submission by approximately one year compared to original projections based on the readout of the OS primary endpoint that remains anticipated in 2023. We do our best to conduct OVAL study in Japan in order to achieve BLA as early as possible in consultation with Regulatory Agency in Japan.

This news release will not affect our business results for the fiscal year ending March 2022. This is expected to be completed within the fiscal year. The OVAL study is the final stage before applying for approval. As Japan began to take part in this global phase III trial as it was already underway, we are able to quickly pursue approval by significantly shortening the development period and reducing development costs. We expect to monetize the product by selling it after its approval.

Platinum-Resistant Ovarian Cancer

In Japan, over 10,000 people are affected by ovarian cancer, with 5,000 associated deaths annually. Platinum-based anti-cancer drugs are the first-line treatment for ovarian cancer, which is said to have a relatively high sensitivity to them. A case is judged to be platinum-resistant ovarian cancer if an progressive disease is observed within six months of platinum therapy. There is a great unmet medical need for such patients with the disease who require new therapies.

Outline of the global phase III trial (OVAL study)

Indication:	Platinum-Resistant Ovarian Cancer
Area:	USA, Israel, EU, Japan
Enrollment:	400 patients (30 of these patients will be enrolled from Japan)
	VB-111 + paclitaxel: 200 patients
	vs.
	placebo + paclitaxel: 200 patients
Primary endpoint:	Overall survival(OS), progression free survival (PFS)

VB-111

VB-111 is a unique therapy that features two mechanisms inducing apoptosis in vascular endothelial cells of tumors and causing an immune response to tumors. It will be administered intravenously to the entire body, which is unusual in gene therapy. The drug is expected to have more indications for solid carcinomas. Currently, VBL and other entities are developing VB-111 for recurrent malignant glioblastomas and colorectal cancer in other countries.