

NB: this is a summary translation of the press release original drafted in Japanese for the disclosure required in compliance with the TSE regulations.

October 16, 2019

Company Name: Oncolys BioPharma Inc.
Representative: Yasuo Urata, President & CEO
(Code: 4588, Listed on Tokyo Stock Exchange Mothers)
Contact: Keiji Yoshimura, Director & Manager-Accounting
Tel: 03-5472-1578

Company Name: Chugai Pharmaceutical Co., Ltd.
Representative: Tatsuro Kosaka, President and CEO
(Code: 4519, Listed on First Section of Tokyo Stock Exchange)
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Change in Designated Applicant under SAKIGAKE Designation System Concerning “Telomelysin (OBP-301),” Oncolytic Viral Immunotherapy

TOKYO, October 16, 2019 -- [Oncolys BioPharma Inc.](#) (hereafter, “Oncolys”) and [Chugai Pharmaceutical Co., Ltd.](#) (hereafter, “Chugai”) announced today that the Ministry of Health, Labour and Welfare (“MHLW”) officially accepted the application on October 15, 2019, jointly filed by both companies to change the designated applicant of the SAKIGAKE Designation for Telomelysin (OBP-301) (hereafter, “Telomelysin”) an oncolytic viral immunotherapy, in which both companies concluded an exclusive license agreement on April 8, 2019.

Oncolys initiated dosing of a corporate initiated Phase I clinical trial for Telomelysin-radiation combination therapy for esophageal cancer in July 2017. Both companies have entered into an agreement on April 8, 2019 that Oncolys will grant an exclusive license, with sublicensing rights, to Chugai concerning the development, manufacturing and marketing in Japan and Taiwan, as well as exclusive option rights concerning the worldwide development, manufacturing and marketing excluding Japan, Taiwan, China, Hong Kong and Macau to Chugai. On the same day, Telomelysin was granted SAKIGAKE Designation by MHLW. The acceptance of the change in designated applicant by MHLW is on the ground that the development of Telomelysin will be transferred from Oncolys to Chugai under the exclusive license agreement concluded between both companies in April 2019. Both companies will continue to work together to promote the development of Telomelysin.

Change of designated information:

	Series	No.	Designation Date	Designated Product Name	Designated Applicant	Expected Indication
Before	4 th	1	April 8, 2019	OBP-301	Oncolys BioPharma Inc.	Unresectable, chemotherapy-intolerant or resistant, locally advanced esophageal cancer
After	(Same as above)				Chugai Pharmaceutical Co., Ltd.	(Same as above)

【References】

Announced on April 8, 2019:

- Notice of Capital and Business Alliance Agreement and Issuance of New Shares through a Third-Party Allotment (Japanese only)
<https://ssl4.eir-parts.net/doc/4588/tdnet/1690513/00.pdf>
- Conclusion of Exclusive Licensing and Capital Tie-up Agreements Concerning “Telomelysin (OBP-301),” Oncolytic Viral Immunotherapy
<https://ssl4.eir-parts.net/doc/4588/announcement9/51655/00.pdf>
https://www.chugai-pharm.co.jp/english/news/detail/20190408163000_610.html
- Oncolytic Viral Immunotherapy Telomelysin (OBP-301) received Japanese MHLW’s SAKIGAKE Designation for the Treatment of esophageal cancer (Japanese only)
<https://ssl4.eir-parts.net/doc/4588/tdnet/1690533/00.pdf>

Inquiries

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