April 4, 2022
Nobelpharma Co., Ltd.

Pleurodesis Agent “Unitalc® Intrapleural 4g”
Additional Indication Approved

Nobelpharma Co., Ltd. (Headquarters: Chuo-ku, Tokyo, Managing Director & CEO: Jin Shiomura), announced today, that additional indication as shown below was approved for the pleurodesis agent "Unitarc® Intrapleural 4g" (nonproprietary name: talc) on March 28, 2022.

"Unitalc® Intrapleural 4g" is a pleurodesis agent containing ground and sorted talc (natural hydrated magnesium silicate). In Japan, this agent, received marketing approval in September 2013 for the indication of "prevention of recurrent malignant pleural effusion," was additionally approved for the indication of "inoperable secondary intractable pneumothorax."

While surgery to remove a lung lesion is generally performed to treat secondary intractable pneumothorax, surgical treatment becomes difficult in patients with poor general condition from complications such as cardiac depression or with considerable risks of postoperative pulmonary fistula due to concomitant emphysema. For such secondary intractable pneumothorax patients intolerable to surgery, procedures including bronchial embolization to physically close bronchial fistula and pleurodesis to stick lung to chest wall by putting irritant drug into pleural space are considered.

Treatment plans vary depending on the condition of fistula among others and bronchial embolization and pleurodesis are generally performed alone or in combination, and yet at the same time, there exist a certain number of patients unable to undergo bronchial embolization because of the difficulties of identifying fistula.

With this approval of the additional indication, Unitalc® has become the only drug for pleurodesis having the indication of secondary intractable pneumothorax in Japan. We are pleased that Unitalc® will be a new option for the treatment of inoperable secondary intractable pneumothorax.

We will continue to contribute to society by providing critical but neglected pharmaceuticals and medical devices.

Extract of the Additional “Indication”

“Indication”

○Inoperable Secondary Intractable Pneumothorax

“Dosage and Administration” (Common with suppression of re-retention of malignant pleural effusion)

In general, for adults, the drug (4g/vial) is suspended in 50 mL of Japanese Pharmacopoeia saline and injected into pleural cavity.

On June 21, 2021, Unitalc® was designated as an orphan drug for then expected indication of "inoperable secondary intractable pneumothorax."

[Designation number: (R3) No. 517].

[Contact for inquiries regarding this matter]
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