



# News Release

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## **TAKECAB® Now Available for the Treatment of Acid-related Diseases in Japan**

- TAKECAB®, discovered by Takeda for the treatment of acid-related disease, is now available in Japan.
- Takeda and Otsuka executed an agreement at the end of March 2014 to co-promote TAKECAB® (for the treatment of acid-related diseases) in Japan. Under the agreement, the two companies will conduct informational activities for healthcare professionals with the aim of addressing unmet clinical needs in the treatment of acid-related diseases.
- Otsuka will receive from Takeda co-promotion fees based on sales levels of TAKECAB® (in accordance with conditions specified in the agreement).

**Osaka and Tokyo, Japan, February 26, 2015** –Takeda Pharmaceutical Company Limited (Head office: Chuo-ku, Osaka; President and COO: Christophe Weber; “Takeda”) and Otsuka Pharmaceutical Company, Limited (Head office: Chiyoda-ku, Tokyo; President and Representative Director: Tatsuo Higuchi; “Otsuka”) announced today that TAKECAB® 10 mg and TAKECAB® 20 mg (generic name: Vonoprazan fumarate, hereafter “TAKECAB”), discovered by Takeda for the treatment of acid-related diseases, is now available in Japan.

TAKECAB, discovered by Takeda, is a new medicine for treating acid-related diseases with a novel mechanism of action called potassium-competitive acid blockers (P-CABs) which competitively inhibits the binding of potassium ions to  $H^+, K^+$ -ATPase (also known as the proton pump) in the final step of gastric acid secretion in gastric parietal cells. Vonoprazan fumarate has fast-acting, strong and sustained acid secretion inhibitory effects. Takeda and Otsuka executed an agreement at the end of March 2014 to co-promote TAKECAB in Japan.

“Ever since our company launched TAKEPRON® more than two decades ago, we have been supporting patients suffering from acid-related diseases and healthcare professionals who are providing them with treatment,” said Masato Iwasaki, Ph.D., Director and President, Japan Pharma Business Unit of Takeda. “I am delighted that together with Otsuka, an excellent co-promotion partner, we are able to offer a new treatment option to address the unmet medical needs in the gastrointestinal field. Through TAKECAB, we will make further contributions to the treatment of acid-related disease.”

“From diagnosis through to treatment Otsuka is contributing broadly in the gastrointestinal field – Mucosta® is a novel medicine for gastric ulcers and our diagnostic system for helicobacter pylori infections is an excellent complement to it,” said Susumu Tamai, Executive Director and Executive Operating Officer, Pharmaceutical Marketing Headquarters of Otsuka. “We are very enthusiastic about entering this collaboration with Takeda in Japan on TAKECAB, an eagerly awaited new treatment for acid-related diseases. We strive to develop innovative medicines and diagnostic drugs to improve the quality of life of many patients.”

# <References>

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| Product name              | TAKECAB®   |
| Generic name              | Vonoprazan fumarate  |
| Indications               | <ul style="list-style-type: none"> <li>○ Gastric ulcer, duodenal ulcer, reflux esophagitis, prevention of recurrence of gastric or duodenal ulcer during low-dose aspirin administration, prevention of recurrence of gastric or duodenal ulcer during non-steroidal anti-inflammatory drug (NSAID) administration</li> <li>○ Adjunct to <i>Helicobacter pylori</i> eradication in the following settings:<br/>Gastric ulcer, duodenal ulcer, gastric mucosa-associated lymphatic tissue (MALT) lymphoma, idiopathic thrombocytopenic purpura, the stomach after endoscopic resection of early stage gastric cancer, or <i>Helicobacter pylori</i> gastritis</li> </ul>  |
| Dosage and administration | <ul style="list-style-type: none"> <li>○ Gastric ulcer, duodenal ulcer<br/>The usual adult dosage for oral use is 20 mg of Vonoprazan administered orally once daily an 8-week treatment for gastric ulcer and a 6-week treatment for duodenal ulcer.</li> <li>○ Reflux esophagitis<br/>The usual adult dose for oral use is 20 mg of Vonoprazan administered once daily for a total of 4 weeks of treatment. If that dosing proves insufficient, the administration should be extended, but for no longer than 8 weeks of treatment.<br/>For the maintenance therapy of reflux esophagitis showing recurrence and recrudescence, the dose for oral use is 10 mg once daily. However, when the efficacy is inadequate, the dosage may be increase up to 20 mg once daily.</li> <li>○ Prevention of recurrence of gastric or duodenal ulcer during low-dose aspirin administration<br/>The usual adult dosage is one tablet of 10 mg of Vonoprazan administered orally once daily.</li> <li>○ Prevention of recurrence of gastric or duodenal ulcer during non-steroidal anti-inflammatory drug (NSAID) administration<br/>The usual adult dosage is one tablet of 10 mg of Vonoprazan administered orally once daily</li> <li>○ Adjunct to <i>Helicobacter pylori</i> eradication:<br/>For adults, the following three-drug regimen should be administered orally at the same time twice daily for seven days: 20 mg dose of Vonoprazan, 750 mg (potency) dose of amoxicillin hydrate, and 200 mg (potency) dose of clarithromycin. The dose of clarithromycin may be increased as clinically warranted. However, dosage should not exceed 400 mg (potency)/dose twice daily.<br/>If <i>Helicobacter pylori</i> eradication with a three-drug regimen comprising a proton pump inhibitor, amoxicillin hydrate and clarithromycin has been unsuccessful, as an alternative treatment, adults should be administered the following three drugs orally twice daily for seven days: 20 mg dose of Vonoprazan, 750 mg (potency) dose of amoxicillin hydrate, and 250 mg dose of metronidazole.</li> </ul> |
| NHI Drug Price            | 10 mg 160.10 yen, 20 mg 240.20 yen   |

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### **About the co-promotion agreement**

The details of this agreement are as below:

- Takeda will receive from Otsuka an up-front payment of 20 billion yen and a milestone payment upon regulatory approval.
- Otsuka will receive from Takeda a co-promotion fee based on the sales amount (based on conditions specified in the contract).
- Territory: Japan

Further details are not disclosed.

### **About Takeda Pharmaceutical Company Limited**

Located in Osaka, Japan, Takeda is a research-based global company with its main focus on pharmaceuticals. As the largest pharmaceutical company in Japan and one of the global leaders of the industry, Takeda is committed to strive towards better health for people worldwide through leading innovation in medicine. Additional information about Takeda is available through its corporate website, [www.takeda.com](http://www.takeda.com).

### **About Otsuka Pharmaceutical Company, Limited**

Otsuka is a global healthcare company with the corporate philosophy: “Otsuka – people creating new products for better health worldwide.” Otsuka researches, develops, manufactures and markets innovative and original products, with a focus on pharmaceutical products for the treatment of diseases and nutraceutical products for the maintenance of everyday health. Otsuka invites you to visit its global website at <https://www.otsuka.co.jp/en/>.

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