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Announcement of Termination of Global License Agreements for Renal Anemia Treatment with Akebia Therapeutics, Inc.

Otsuka Pharmaceutical Co., Ltd. (Otsuka) announces that it has decided to terminate its global license agreements with Akebia Therapeutics, Inc. (Akebia) for vadadustat (generic name), under development as an oral treatment for anemia associated with chronic kidney disease (renal anemia). These licenses were signed in in December 2016 for the U.S. and April 2017 for Europe and other regions.

Otsuka and Akebia had been co-developing vadadustat for renal anemia, however in March this year, Akebia received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA). As a result, Otsuka has decided to terminate its co-development of vadadustat and has notified Akebia of the termination of its global license agreements.

Otsuka is expanding globally in the cardiovascular and renal therapeutic areas as one of its priority therapeutic areas. Otsuka will continue its vigorous research programs on new treatments for patients with unfulfilled medical needs who eagerly await new treatment choices.

Otsuka Holdings has recorded an impairment loss of 23.6 billion yen related to vadadustat in the first quarter of FY2022. There is no change to our FY2022 forecast at this point, because 4 global products* which are the growth driver in pharmaceutical business is progressing steadily and are going to gain in other income due to inclusion of Cullinan Pearl Corp. in the scope of consolidation in the second quarter and beyond.

* 4 Global Products (*Abilify Maintena, REXULTI, Samsca/JINARC/JYNARQUE, LONSURF*),