Japan Tobacco Inc. Clinical Development as of October 31, 2016

＜In-house development＞

Code （Generic Name）	Potential Indication/Dosage form	Mechanism		Phase	Note
emtricitabine/ tenofovir alafenamide	HIV infection /Oral	Nucleoside reverse transcriptase inhibitor	Suppresses blood HIV levels by inhibiting the activity of reverse transcriptase, an enzyme involved in the replication of HIV.	NDA filed (Japan)	In-license (Gilead Sciences)
JTT-851	Type 2 diabetes mellitus /Oral	G protein-coupled receptor 40 agonist	Decreases blood glucose by stimulation of glucose-dependent insulin secretion.	Phase2 (Japan) Phase2 (Overseas)	In-house
JTZ-951	Anemia associated with chronic kidney disease /Oral	HIF-PHD inhibitor	Increases red blood cells by stimulating production of erythropoietin, an erythropoiesis-stimulating hormone, via inhibition of HIF-PHD.	Phase2(Japan) Phase1(Overseas)	In-house
JTE-052	Autoimmune/allergic diseases /Oral, Topical	JAK inhibitor	Suppresses overactive immune response via inhibition of Janus kinase (JAK) related to immune signal.	Phase2(Japan)	In-house Co-development with Torii
JTE-051	Autoimmune/allergic diseases /Oral	Interleukin-2 inducible T cell kinase inhibitor	Suppresses overactive immune response via inhibition of the signal to activate T cells related to immune response.	Phase1(Overseas)	In-house
JTT-251	Type 2 diabetes mellitus /Oral	PDHK inhibitor	Decreases blood glucose by activation of pyruvate dehydrogenase (PDH) related to carbohydrate metabolism.	Phase1(Overseas)	In-house
JTK-351	HIV infection /Oral	HIV integrase inhibitor	Suppresses blood HIV levels by inhibiting the activity of integrase, an enzyme involved in the replication of HIV.	Phase1(Japan)	In-house
JTE-451	Autoimmune/allergic diseases /Oral	RORγ antagonist	Suppresses overactive immune response via inhibition of ROR γ related to Th 17 activation.	Phase1(Overseas)	In-house
JTT-751 （ferric citrate）	Iron-deficiency anemia/Oral	Oral iron replacement	Corrects iron-deficiency anemia by using absorbed Iron for synthesis of hemoglobin.	Phase2(Japan)	In-license （Keryx Biopharmaceuticals） Co-development with Torii *additional indication

Clinical trial phase presented above is based on the first dose.

＜Licensed compounds＞

Compound （JT's code）	Licensee	Mechanism		Note
trametinib	Novartis	MEK inhibitor	Inhibits cellular growth by specifically inhibiting the activity of MAPK/ERK Kinase (MEK1/2).	NSCLC, trametinib+dabrafenib U.S. and EU marketing approvals submitted
Anti-ICOS monoclonal antibody	MedImmune	ICOS antagonist	Suppresses overactive immune response via inhibition of ICOS which regulates activation of T cells.	
JTE-052	LEO Pharma	JAK inhibitor	Suppresses overactive immune response via inhibition of Janus kinase (JAK) related to immune signal.	
JTZ-951	JW Pharmaceutical	HIF-PHD inhibitor	Increases red blood cells by stimulating production of erythropoietin, an erythropoiesis-stimulating hormone, via inhibition of HIF-PHD.	

Updates since the previous announcement on August 1, 2016:

＜In-house development＞
・emtricitabine/tenofovir alafenamide: filed NDA for marketing approval in Japan. (August 12, 2016)
・JTE-052: started co-development with Torii Pharmaceutical Co.,Ltd.

＜Licensed compounds＞
・Licensed exclusive rights to JW Pharmaceutical for further development and marketing JTZ-951 for the treatment of anemia associated with chronic kidney disease (CKD) in Republic of Korea.(October 14, 2016)