ONON enters into license agreement with Celyad for its allogeneic CAR T-cell therapy (NKR-2)

ONOPHARMACEUTICALCO.,LTD.(Osaka,Japan;President,RepresentativeDirectorandCEO,GyoSagara;“ONO”)todayannouncedthatithasenteredintoanexclusivelicenseagreementwithCelyad(Mont-Saint-Guibert,Belgium)todelyzeandcommercializeCelyad’sNKG2D-ligandtargetingallogeneicCAR T-celltherapy,NKR-2,inJapan,SouthKoreaandTaiwan.

ONOWillpaytoCelyadanupfrontpaymentofJPY1.25billionatclosingoftheagreementandamaximumtotalofJPY30.075billionthereaftermilestonesbasedondevelopmentstageaswellasupontheachievementofspecifiednetsalesthreshold.TheagreementalsocallsfordoubledigitroyaltiesonnetsalesinONO’sterritories.


GyoSagara,President,RepresentativeDirectorandCEOofONO,said:“Weareverypedictedtolcollaboratewiththeleadingcelltherapycompany,Celyad,foritsdistinctimmuno-oncologycandidates.Celyad’sNKR-2isbackedbycutting-edge-scienceandwbelievethatifcanbeatnewtherapeuticoptionforpatientswhonotcuredwithexistingtherapies.”

ChristianHomsy,MD,MBA,CEOofCelyad,said:“WeareverypleasedtocollaboratewithONOandtoactivatethedevolutionofourNKR-2T-cellallogeneicplatforminJapan,SouthKoreaandTaiwan.ThislicenseagreementisagreatopportunityforCelyadtoexpansethescopeofitsimmuno-oncologyclinicalprogramsandbringthisbreakthroughsciencetomanypatientsintheseregionsofAsiaand,alongwiththeU.S.andtheEU.Further,thislicenseagreementvalidatesourNKR-2approachanditshighpotentialbyONO,thelateonimmuno-oncologyinAsia.”

GeorgesRawadi,Ph.D.,M.S.,VPBusinessDevelopmentofCelyad,said:“Celyad surroundsitselfwiththebestimmuno-oncologyexpertsintheworldtodevelopitsNKR T-cellplatform.ThisiswhywehaveenteredthisagreementwithONO.Throughthiscommerciallicenseagreement,CelyadaimstoexpandtheclinicalandcommercialpotentialofitsallogeneicNKR-2T-cellimmunotherapiesworldwide.”

AboutNKR-2

ExistingCAR T-cellsareengineeredusingconstructsencodinganantigenbinding/sitesofantibodyfortargetmoleculeandthesignalingdomainsofT-cellreceptorcomplex.IncontrasttoexistingCAR T-cells,Celyad’sleadimmuno-oncologyproductcandidate,NKR-2,isAT-CellencodedtoexpressthehumanNaturalKilleractivatingreceptor,NKG2D.UsingthehumanNaturalKillercellreceptor,unliketraditionalCARtechnologies,hasthepotentialto:
• Bind to 8 different ligands that are expressed by a vast majority of cancer cells, both hematological and solid malignancies.

• Target and kill tumors as well as the blood vessels that feed them and also express the ligands of the NKG2D receptor.

• Attack regulatory T-cells in tumor microenvironment and remove the immunosuppressiveness.

• Induce adaptive auto-immune response resulting in the creation of a long term cell memory against the targeted tumor.

Autologous NKR-2 is prepared from patient’s T-cell extract from own blood, which is processed into NKR-2 outside the body and then administered to the patient. On the other hand, allogeneic NKR-2, which ONO obtained license from Celyad, is derived from healthy donors’ blood and processed into NKR-2. An inhibitory mechanism against TCR signaling is applied to allogeneic NKR-2 to avoid GvHD in the patients. The product could be used off-the-shelf for wide range of patients.

The research underlying this technology was originally conducted by Dartmouth College Professor Charles L. Sentman, and has been published in numerous peer-reviewed publications. Autologous NKR-2 has an active Investigational New Drug (IND) application with the FDA for a Phase I clinical trial. The trial is designed to assess the safety and feasibility of NKR-2 in acute myeloid leukemia and multiple myeloma patients, with secondary endpoints including clinical activity.

About Celyad

Founded in 2007, and based in Belgium, Celyad is a leader in engineered cell therapy with clinical programs initially targeting indications in oncology and cardiology. Celyad is developing its lead cardiovascular disease product candidate, C-Cure®, for the treatment of ischemic heart failure, and has completed enrollment of a Phase III trial in Europe and Israel. In addition, the Company is developing a next generation portfolio of CAR T-cell therapies that utilize human Natural Killer cell receptors for the treatment of numerous blood and solid cancers. Its lead oncology product candidate, NKR-2 (NKG2D CAR T-cell), entered a Phase I clinical trial in April 2015.

Celyad’s ordinary shares are listed on Euronext Brussels and Euronext Paris under the ticker symbol CYAD and Celyad’s American Depositary Shares are listed on the NASDAQ Global Market under the ticker symbol CYAD.

To learn more about Celyad, please visit www.celyad.com

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