Patient-Reported Outcomes from the CARTITUDE-4 Study Showed Clinically Meaningful Improvements in Health-Related Quality of Life and Reductions in Multiple Myeloma Symptoms Following Treatment with CARVYKTI® (ciltacabtagene autoleucel)

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- *In CARTITUDE-4, CARVYKTI® demonstrated clinically meaningful improvements in patient-reported outcomes when compared to standard of care*
- *The as-treated population in CARTITUDE-4 demonstrated strong rates of progression-free survival and overall response*
- *Longer-term data from CARTITUDE-2 showed deep and durable responses in earlier lines of treatment among patients in Cohort A and Cohort B*

SOMERSET, N.J.--(BUSINESS WIRE)--Dec. 11, 2023-- Legend Biotech Corporation (NASDAQ: LEGN) (Legend Biotech), a global biotechnology company developing, manufacturing, and commercializing novel therapies to treat life-threatening diseases, announced today patient-reported outcome (PRO) data from the Phase 3 CARTITUDE-4 study from an oral presentation at the 2023 American Society of Hematology (ASH) Annual Meeting (Abstract #1063). These data showed clinically meaningful improvement in health-related quality of life following a single CARVYKTI® (ciltacabtagene autoleucel; cilta-cel) infusion in adults lenalidomide-refractory multiple myeloma (MM) who received one to three prior lines of therapy (LOT), compared to patients treated with the standard of care (SOC) treatment regimens of either pomalidomide, bortezomib and dexamethasone (PVd) or daratumumab, pomalidomide and dexamethasone (DPd).[1] The PRO data also demonstrated meaningful reductions in disease-specific symptoms after a single infusion for patients in the CARVYKTI® arm, while patients in the SOC treatment arm trended toward worsening or lower degrees of improvement from baseline for most domains and symptoms.

Eligible patients in the CARTITUDE-4 study had lenalidomide-refractory MM, and had one to three prior LOT, including a proteasome inhibitor (PI) and an immunomodulatory drug. Four hundred nineteen patients were randomized, with 208 patients in the CARVYKTI® arm and 211 patients in the SOC arm. At the clinical cut-off on November 1, 2022, 99 patients in the CARVYKTI® arm and 66 patients in the SOC arm had baseline and 12-month PRO assessments, representing data prior to disease progression. When compared to SOC, patients who received the CARVYKTI® infusion exceeded clinically meaningful thresholds for average improvement from baseline to 12 months in global health status (10.1 points vs. -1.5 points), pain (-10.2 points vs. -3.9 points), and the visual analogue scale (8.0 points vs. 1.4 points).[1]

“The CARTITUDE-4 data presented today reinforce the impact that a single infusion of CARVYKTI ® may provide to patients,” said Roberto Mina, Assistant Professor, Division of Hematology, Department of Molecular Biotechnology and Health Sciences, University of Torino, Turin, Italy.

When compared to SOC, the PRO data for CARVYKTI® neared clinically meaningful thresholds when evaluating improvements in fatigue (-9.1 points vs. 2.8 points) and emotional functioning (9.5 points vs. 2.2 points), and numerically favored CARVYKTI® for all other domains established by the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 (EORTC QLQ-C30; 100-point scale). The median time until MM symptom worsening in the CARVYKTI® arm was 23.7 months compared to 18.9 months in the SOC arm (hazard ratio [HR], 0.42), as measured with the Multiple Myeloma Symptom and Impact Questionnaire (MySIm-Q; 5-point scale).[1]

CARTITUDE-4 As-Treated Analysis Illustrated Favorable Progression-Free Survival (PFS) Rate

An additional analysis of the CARTITUDE-4 study data was presented as a poster (Abstract #4866) at the ASH Annual Meeting. At the clinical cut-off, 176 of the 208 patients were randomized to the CARVYKTI® treatment arm. The median age of this patient population was 61 years and 34 percent had received 1 prior LOT. At a median follow-up of 16 months following randomization, 22 percent of patients received one bridging therapy cycle, 59 percent received two cycles and 18 percent received 3 cycles, and disease burden was effectively controlled across the as-treated patient set during bridging therapy.[2]

At 12 months following infusion, the PFS rate was 85 percent, and the overall survival (OS) rate was 92 percent. Median PFS had not been reached. The overall response rate (ORR) was 99 percent and 86 percent of patients achieved complete response or better (≥CR). Of the minimum residual disease- (MRD) evaluable patients (n=144), 77 percent achieved both MRD negativity and ≥CR.[2]

The most common CAR-T cell-related toxicity was Cytokine Release Syndrome (CRS) at 76 percent (1 percent grade 3), the neurotoxicity rate was 21 percent (3 percent grade 3/4), and Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) occurred in 5 percent of patients (no grade 3/4). Other neurotoxicities occurred in 17 percent of patients (2 percent grade 3/4). By the clinical cut-off, CRS and ICANS had resolved in all patients.[2]

Data from CARTITUDE-2 Cohorts A and B Demonstrated Deep and Durable Responses

During a second oral presentation, longer term efficacy and safety data from CARTITUDE-2 cohorts A and B were also presented at the ASH Annual Meeting (Abstract #1021). At a median follow-up of approximately 29 months, patients with lenalidomide-refractory MM after one to three lines of therapy (Cohort A) and those with early relapse (Cohort B) that were treated with CARVYKTI® in earlier lines of therapy experienced deep and durable responses .[3]

In both Cohort A (n=20) and Cohort B (n=19), treatment with CARVYKTI® led to overall response rates of 95 percent (≥CR, 90 percent) and 100 percent (≥CR, 90 percent), respectively. In Cohort A, the 24-month PFS rate was 75 percent, and the 24-month OS rate was 75 percent. As for cohort B, the 24-month PFS and OS rates were 73 percent and 84 percent, respectively. There were no new CAR-T-related safety signals for Cohorts A and B, however one additional CAR-T related cell neurotoxicity (grade 2) was reported in cohort B.[3]

"We believe the safety and efficacy data presented from the CARTITUDE Clinical Development program at the 2023 ASH Annual Meeting support our continuous efforts to bring CARVYKTI® to myeloma patients in various stages of disease progression," said Ying Huang, Ph.D., Chief Executive Officer of Legend Biotech. "Part of our mission is to improve the lives of patients worldwide, and we are excited that the CARTITUDE-4 PRO analyses indicate that patients may experience a higher health-related quality of life following a single CARVYKTI® infusion."

Disclosure: Dr. Mina has provided consulting, advisory, and speaking services to Legend Biotech

CARVYKTI® Important Safety Information

CARVYKTI® INDICATIONS AND USAGE

CARVYKTI® (ciltacabtagene autoleucel) is a B-cell maturation antigen (BCMA)-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory multiple myeloma, after four or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.

CARVYKTI® IMPORTANT SAFETY INFORMATION

WARNING: CYTOKINE RELEASE SYNDROME, NEUROLOGIC TOXICITIES, HLH/MAS, and PROLONGED and RECURRENT CYTOPENIA

Cytokine Release Syndrome (CRS), including fatal or life-threatening reactions, occurred in patients following treatment with CARVYKTI®. Do not administer CARVYKTI® to patients with active infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab or tocilizumab and corticosteroids.

Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS), which may be fatal or life-threatening, occurred following treatment with CARVYKTI®, including before CRS onset, concurrently with CRS, after CRS resolution, or in the absence of CRS. Monitor for neurologic events after treatment with CARVYKTI®. Provide supportive care and/or corticosteroids as needed.

Parkinsonism and Guillain-Barré syndrome and their associated complications resulting in fatal or life-threatening reactions have occurred following treatment with CARVYKTI®.

Hemophagocytic Lymphohistiocytosis/Macrophage Activation Syndrome (HLH/MAS), including fatal and life-threatening reactions, occurred in patients following treatment with CARVYKTI®. HLH/MAS can occur with CRS or neurologic toxicities.

Prolonged and/or recurrent cytopenias with bleeding and infection and requirement for stem cell transplantation for hematopoietic recovery occurred following treatment with CARVYKTI®.

CARVYKTI® is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the CARVYKTI® REMS Program.

WARNINGS AND PRECAUTIONS

CYTOKINE RELEASE SYNDROME (CRS) including fatal or life-threatening reactions, occurred following treatment with CARVYKTI® in 95% (92/97) of patients receiving ciltacabtagene autoleucel. Grade 3 or higher CRS (2019 ASTCT grade) occurred in 5% (5/97) of patients, with Grade 5 CRS reported in 1 patient. The median time to onset of CRS was 7 days (range: 112 days). The most common manifestations of CRS included pyrexia (100%), hypotension (43%), increased aspartate aminotransferase (AST) (22%), chills (15%), increased alanine aminotransferase (ALT) (14%) and sinus tachycardia (11%). Grade 3 or higher events associated with CRS included increased AST and ALT, hyperbilirubinemia, hypotension, pyrexia, hypoxia, respiratory failure, acute kidney injury, disseminated intravascular coagulation, HLH/MAS, angina pectoris, supraventricular and ventricular tachycardia, malaise, myalgias, increased C-reactive protein, ferritin, blood alkaline phosphatase and gamma-glutamyl transferase.

Identify CRS based on clinical presentation. Evaluate for and treat other causes of fever, hypoxia, and hypotension. CRS has been reported to be associated with findings of HLH/MAS, and the physiology of the syndromes may overlap. HLH/MAS is a potentially life-threatening condition. In patients with progressive symptoms of CRS or refractory CRS despite treatment, evaluate for evidence of HLH/MAS.

Sixty-nine of 97 (71%) patients received tocilizumab and/or a corticosteroid for CRS after infusion of ciltacabtagene autoleucel. Forty-four (45%) patients received only tocilizumab, of whom 33 (34%) received a single dose and 11 (11%) received more than one dose; 24 patients (25%) received tocilizumab and a corticosteroid, and one patient (1%) received only corticosteroids. Ensure that a minimum of two doses of tocilizumab are available prior to infusion of CARVYKTI®.

Monitor patients at least daily for 10 days following CARVYKTI® infusion at a REMS-certified healthcare facility for signs and symptoms of CRS. Monitor patients for signs or symptoms of CRS for at least 4 weeks after infusion. At the first sign of CRS, immediately institute treatment with supportive care, tocilizumab, or tocilizumab and corticosteroids.

Counsel patients to seek immediate medical attention should signs or symptoms of CRS occur at any time.

NEUROLOGIC TOXICITIES, which may be severe, life-threatening or fatal, occurred following treatment with CARVYKTI®. Neurologic toxicities included ICANS, neurologic toxicity with signs and symptoms of parkinsonism, Guillain-Barré Syndrome, peripheral neuropathies, and cranial nerve palsies. Counsel patients on the signs and symptoms of these neurologic toxicities, and on the delayed nature of onset of some of these toxicities. Instruct patients to seek immediate medical attention for further assessment and management if signs or symptoms of any of these neurologic

toxicities occur at any time.

Overall, one or more subtypes of neurologic toxicity described below occurred following ciltacabtagene autoleucel in 26% (25/97) of patients, of which 11% (11/97) of patients experienced Grade 3 or higher events. These subtypes of neurologic toxicities were also observed in two ongoing studies.

Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS): Patients may experience fatal or life-threatening ICANS following treatment with CARVYKTI®, including before CRS onset, concurrently with CRS, after CRS resolution, or in the absence of CRS. ICANS occurred in 23% (22/97) of patients receiving ciltacabtagene autoleucel including Grade 3 or 4 events in 3% (3/97) and Grade 5 (fatal) events in 2% (2/97). The median time to onset of ICANS was 8 days (range 1-28 days). All 22 patients with ICANS had CRS. The most frequent (≥5%) manifestation of ICANS included encephalopathy (23%), aphasia (8%) and headache (6%).

Monitor patients at least daily for 10 days following CARVYKTI® infusion at the REMS-certified healthcare facility for signs and symptoms of ICANS. Rule out other causes of ICANS symptoms. Monitor patients for signs or symptoms of ICANS for at least 4 weeks after infusion and treat promptly. Neurologic toxicity should be managed with supportive care and/or corticosteroids as needed.

Parkinsonism: Of the 25 patients in the CARTITUDE-1 study experiencing any neurotoxicity, five male patients had neurologic toxicity with several signs and symptoms of parkinsonism, distinct from immune effector cell-associated neurotoxicity syndrome (ICANS). Neurologic toxicity with parkinsonism has been reported in other ongoing trials of ciltacabtagene autoleucel. Patients had parkinsonian and non-parkinsonian symptoms that included tremor, bradykinesia, involuntary movements, stereotypy, loss of spontaneous movements, masked facies, apathy, flat affect, fatigue, rigidity, psychomotor retardation, micrographia, dysgraphia, apraxia, lethargy, confusion, somnolence, loss of consciousness, delayed reflexes, hyperreflexia, memory loss, difficulty swallowing, bowel incontinence, falls, stooped posture, shuffling gait, muscle weakness and wasting, motor dysfunction, motor and sensory loss, akinetic mutism, and frontal lobe release signs. The median onset of parkinsonism in the 5 patients in CARTITUDE-1 was 43 days (range 15-108) from infusion of ciltacabtagene autoleucel.

Monitor patients for signs and symptoms of parkinsonism that may be delayed in onset and managed with supportive care measures. There is limited efficacy information with medications used for the treatment of Parkinson's disease, for the improvement or resolution of parkinsonism symptoms following CARVYKTI® treatment.

Guillain-Barré Syndrome: A fatal outcome following Guillain-Barré Syndrome (GBS) has occurred in another ongoing study of ciltacabtagene autoleucel despite treatment with intravenous immunoglobulins. Symptoms reported include those consistent with Miller-Fisher variant of GBS, encephalopathy, motor weakness, speech disturbances and polyradiculoneuritis.

Monitor for GBS. Evaluate patients presenting with peripheral neuropathy for GBS. Consider treatment of GBS with supportive care measures and in conjunction with immunoglobulins and plasma exchange, depending on severity of GBS.

Peripheral Neuropathy: Six patients in CARTITUDE-1 developed peripheral neuropathy. These neuropathies presented as sensory, motor, or sensorimotor neuropathies. Median time of onset of symptoms was 62 days (range 4-136 days), median duration of peripheral neuropathies was 256 days (range 2-465 days) including those with ongoing neuropathy. Patients who experienced peripheral neuropathy also experienced cranial nerve palsies or GBS in other ongoing trials of ciltacabtagene autoleucel.

Cranial Nerve Palsies: Three patients (3.1%) experienced cranial nerve palsies in CARTITUDE1. All three patients had 7th cranial nerve palsy; one patient had 5th cranial nerve palsy as well. Median time to onset was 26 days (range 21-101 days) following infusion of ciltacabtagene autoleucel. Occurrence of 3rd and 6th cranial nerve palsy, bilateral 7th cranial nerve palsy, worsening of cranial nerve palsy after improvement, and occurrence of peripheral neuropathy in patients with cranial nerve palsy have also been reported in ongoing trials of ciltacabtagene autoleucel. Monitor patients for signs and symptoms of cranial nerve palsies. Consider management with systemic corticosteroids, depending on the severity and progression of signs and symptoms.

HEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS (HLH)/MACROPHAGE ACTIVATION SYNDROME (MAS): Fatal HLH occurred in one patient (1%), 99 days after ciltacabtagene autoleucel. The HLH event was preceded by prolonged CRS lasting 97 days. The manifestations of HLH/MAS include hypotension, hypoxia with diffuse alveolar damage, coagulopathy, cytopenia, and multi-organ dysfunction, including renal dysfunction. HLH is a life-threatening condition with a high mortality rate if not recognized and treated early. Treatment of HLH/MAS should be administered per institutional standards.

CARVYKTI® REMS: Because of the risk of CRS and neurologic toxicities, CARVYKTI® is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the CARVYKTI® REMS.

Further information is available at https://www.carvyktirems.com/ or 1-844-672-0067.

PROLONGED AND RECURRENT CYTOPENIAS: Patients may exhibit prolonged and recurrent cytopenias following lymphodepleting chemotherapy and CARVYKTI® infusion. One patient underwent autologous stem cell therapy for hematopoietic reconstitution due to prolonged thrombocytopenia.

In CARTITUDE-1, 30% (29/97) of patients experienced prolonged Grade 3 or 4 neutropenia and 41% (40/97) of patients experienced prolonged Grade 3 or 4 thrombocytopenia that had not resolved by Day 30 following ciltacabtagene autoleucel infusion.

Recurrent Grade 3 or 4 neutropenia, thrombocytopenia, lymphopenia, and anemia were seen in 63% (61/97), 18% (17/97), 60% (58/97), and 37% (36/97) after recovery from initial Grade 3 or 4 cytopenia following infusion. After Day 60 following ciltacabtagene autoleucel infusion, 31%, 12% and 6% of patients had a recurrence of Grade 3 or higher lymphopenia, neutropenia and thrombocytopenia, respectively, after initial recovery of their Grade 3 or 4 cytopenia. Eighty-seven percent (84/97) of patients had one, two, or three or more recurrences of Grade 3 or 4 cytopenias after initial recovery of Grade 3 or 4 cytopenia. Six and 11 patients had Grade 3 or 4 neutropenia and thrombocytopenia, respectively, at the time of death.

Monitor blood counts prior to and after CARVYKTI® infusion. Manage cytopenias with growth factors and blood product transfusion support according to local institutional guidelines.

INFECTIONS: CARVYKTI® should not be administered to patients with active infection or inflammatory disorders. Severe, life-threatening or fatal

infections occurred in patients after CARVYKTI® infusion.

Infections (all grades) occurred in 57 (59%) patients. Grade 3 or 4 infections occurred in 23% (22/97) of patients; Grade 3 or 4 infections with an unspecified pathogen occurred in 17%, viral infections in 7%, bacterial infections in 1%, and fungal infections in 1% of patients. Overall, four patients had Grade 5 infections: lung abscess (n=1), sepsis (n=2) and pneumonia (n=1).

Monitor patients for signs and symptoms of infection before and after CARVYKTI® infusion and treat patients appropriately. Administer prophylactic, pre-emptive and/or therapeutic antimicrobials according to the standard institutional guidelines. Febrile neutropenia was observed in 10% of patients after ciltacabtagene autoleucel infusion and may be concurrent with CRS. In the event of febrile neutropenia, evaluate for infection and manage with broad-spectrum antibiotics, fluids, and other supportive care, as medically indicated.

Viral Reactivation: Hepatitis B virus (HBV) reactivation, in some cases resulting in fulminant hepatitis, hepatic failure and death, can occur in patients with hypogammaglobulinemia. Perform screening for Cytomegalovirus (CMV), HBV, hepatitis C virus (HCV), and human immunodeficiency virus (HIV), or any other infectious agents if clinically indicated in accordance with clinical guidelines before collection of cells for manufacturing. Consider antiviral therapy to prevent viral reactivation per local institutional guidelines/clinical practice.

HYPOGAMMAGLOBULINEMIA was reported as an adverse event in 12% (12/97) of patients; laboratory IgG levels fell below 500 mg/dL after infusion in 92% (89/97) of patients. Monitor immunoglobulin levels after treatment with CARVYKTI® and administer IVIG for IgG <400 mg/dL. Manage per local institutional guidelines, including infection precautions and antibiotic or antiviral prophylaxis.

Use of Live Vaccines: The safety of immunization with live viral vaccines during or following CARVYKTI® treatment has not been studied. Vaccination with live virus vaccines is not recommended for at least 6 weeks prior to the start of lymphodepleting chemotherapy, during CARVYKTI® treatment, and until immune recovery following treatment with CARVYKTI®.

HYPERSENSITIVITY REACTIONS have occurred in 5% (5/97) of patients following ciltacabtagene autoleucel infusion. Serious hypersensitivity reactions, including anaphylaxis, may be due to the dimethyl sulfoxide (DMSO) in CARVYKTI®. Patients should be carefully monitored for 2 hours after infusion for signs and symptoms of severe reaction. Treat promptly and manage appropriately according to the severity of the hypersensitivity reaction.

SECONDARY MALIGNANCIES: Patients may develop secondary malignancies. Monitor life-long for secondary malignancies. In the event that a secondary malignancy occurs, contact Janssen Biotech, Inc., at 1-800-526-7736 for reporting and to obtain instructions on collection of patient samples for testing of secondary malignancy of T cell origin.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES: Due to the potential for neurologic events, including altered mental status, seizures, neurocognitive decline, or neuropathy, patients are at risk for altered or decreased consciousness or coordination in the 8 weeks following CARVYKTI® infusion. Advise patients to refrain from driving and engaging in hazardous occupations or activities, such as operating heavy or potentially dangerous machinery during this initial period, and in the event of new onset of any neurologic toxicities.

ADVERSE REACTIONS

The most common non-laboratory adverse reactions (incidence greater than 20%) are pyrexia, cytokine release syndrome, hypogammaglobulinemia, hypotension, musculoskeletal pain, fatigue, infections of unspecified pathogen, cough, chills, diarrhea, nausea, encephalopathy, decreased appetite, upper respiratory tract infection, headache, tachycardia, dizziness, dyspnea, edema, viral infections, coagulopathy, constipation, and vomiting. The most common laboratory adverse reactions (incidence greater than or equal to 50%) include thrombocytopenia, neutropenia, anemia, aminotransferase elevation, and hypoalbuminemia.

Please read full Prescribing Information including Boxed Warning for CARVYKTI®.

ABOUT CARVYKTI® (CILTACABTAGENE AUTOLEUCEL; CILTA-CEL)

Ciltacabtagene autoleucel is a B-cell maturation antigen (BCMA)-directed, genetically modified autologous T-cell immunotherapy, which involves reprogramming a patient's own T-cells with a transgene encoding a chimeric antigen receptor (CAR) that identifies and eliminates cells that express BCMA. BCMA is primarily expressed on the surface of malignant multiple myeloma B-lineage cells, as well as late-stage B-cells and plasma cells. The cilta-cel CAR protein features two BCMA-targeting single domain antibodies designed to confer high avidity against human BCMA. Upon binding to BCMA-expressing cells, the CAR promotes T-cell activation, expansion, and elimination of target cells.[4]

In December 2017, Legend Biotech entered into an exclusive worldwide license and collaboration agreement with Janssen Biotech, Inc. (Janssen) to develop and commercialize cilta-cel.

ABOUT CARTITUDE-4

CARTITUDE-4 (NCT04181827) is an ongoing, international, randomized, open-label Phase 3 study evaluating the efficacy and safety of cilta-cel versus pomalidomide, bortezomib and dexamethasone (PVd) or daratumumab, pomalidomide and dexamethasone (DPd) in adult patients with relapsed and lenalidomide-refractory multiple myeloma who received one to three prior lines of therapy, including a PI and an IMiD. The primary endpoint of the study was progression-free survival.[5]

ABOUT CARTITUDE-2

CARTITUDE-2 (NCT04133636) is an ongoing Phase 2 multicohort study evaluating the safety and efficacy of cilta-cel in various clinical settings (Cohorts A, B, C, D, E, F, G, H). The primary study objective is to measure the percentage of patients with negative minimal residual disease (MRD).[6]

ABOUT MULTIPLE MYELOMA

Multiple myeloma is an incurable blood cancer that starts in the bone marrow and is characterized by an excessive proliferation of plasma cells.[7] In

2023, it is estimated that more than 35,000 people will be diagnosed with multiple myeloma, and more than 12,000 people will die from the disease in the U.S.[8] While some patients with multiple myeloma initially have no symptoms, most patients are diagnosed due to symptoms that can include bone problems, low blood counts, calcium elevation, kidney problems or infections.[9]

ABOUT LEGEND BIOTECH

Legend Biotech is a global biotechnology company dedicated to treating, and one day curing, life-threatening diseases. Headquartered in Somerset, New Jersey, we are developing advanced cell therapies across a diverse array of technology platforms, including autologous and allogeneic chimeric antigen receptor T-cell, gamma-delta T cell (γδ T) and natural killer (NK) cell-based immunotherapy. From our three R&D sites around the world, we apply these innovative technologies to pursue the discovery of safe, efficacious and cutting-edge therapeutics for patients worldwide.

Learn more at www.legendbiotech.com and follow us on X (formerly Twitter) and LinkedIn.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Statements in this press release about future expectations, plans and prospects, as well as any other statements regarding matters that are not historical facts, constitute "forward-looking statements" within the meaning of The Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, statements relating to Legend Biotech's expectations for cilta-cel, expectations for Legend Biotech's product candidates based on clinical trial results,

the potential effect of treatment with cilta-cel and the potential benefits of Legend Biotech's product candidates. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors. Legend Biotech's expectations could be affected by, among other things, uncertainties involved in the development of new pharmaceutical products; unexpected clinical trial results, including as a result of additional analysis of existing clinical data or unexpected new clinical data; unexpected regulatory actions or delays, including requests for additional safety and/or efficacy data or analysis of data, or government regulation generally; unexpected delays as a result of actions undertaken, or failures to act, by our third party partners; uncertainties arising from challenges to Legend Biotech's patent or other proprietary intellectual property protection, including the uncertainties involved in the U.S. litigation process; competition in general; government, industry, and general product pricing and other political pressures; the duration and severity of the COVID-19 pandemic and governmental and regulatory measures implemented in response to the evolving situation; as well as the other factors discussed in the "Risk Factors" section of Legend Biotech's Annual Report on Form 20-F filed with the Securities and Exchange Commission on March 30, 2023 and other filings and furnishings made by Legend Biotech with the U.S. Securities and Exchange Commission on EDGAR at www.sec.gov. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described in this press release as anticipated, believed, estimated or expected. Any forward-looking statements contained in this press release speak only as of the date of this press release. Legend Biotech specifically disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

References

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