Kiniksa Reports Data for Mavrilimumab in COVID-19 Pneumonia and Hyperinflammation and for Vixarelimab in Diseases Characterized by Chronic Pruritus

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– Mavrilimumab treatment protocol in patients with severe COVID-19 pneumonia and hyperinflammation showed improved clinical outcomes compared to matched contemporaneous controls, including earlier weaning from supplemental oxygen, shorter hospitalizations, and no deaths –

– Vixarelimab exploratory Phase 2 trial in diseases characterized by chronic pruritus showed encouraging efficacy results in 4 out of 5 cohorts; plaque psoriasis cohort achieved statistically significant reduction in weekly-average Worst-Itch Numeric Rating Scale (WI-NRS) at Week 8 –

HAMILTON, Bermuda, May 11, 2020 (GLOBE NEWSWIRE) -- Kiniksa Pharmaceuticals, Ltd. (Nasdaq: KNSA) ("Kiniksa"), a biopharmaceutical company focused on discovering, acquiring, developing and commercializing therapeutic medicines for patients with significant unmet medical need, today provided additional data from the open-label treatment protocol with mavrilimumab, an investigational fully-human monoclonal antibody that targets granulocyte macrophage colony stimulating factor receptor alpha (GM-CSFRα), in patients with severe coronavirus 2019 (COVID-19) pneumonia and hyperinflammation. The company also provided data from the exploratory Phase 2 trial for vixarelimab, an investigational fully-human monoclonal antibody that targets oncostatin M receptor beta (OSMRβ), in diseases characterized by chronic pruritus.

"These data are consistent with the encouraging results we have seen across our pipeline to date," said Sanj K. Patel, Chief Executive Officer and Chairman of the Board of Kiniksa. "We are seeing the potential broad utility of mavrilimumab as demonstrated by the treatment protocol in COVID-19 pneumonia and hyperinflammation as well as our clinical collaboration with Kite Gilead in CAR T cytokine storm and our Phase 2 development program in giant cell arteritis. Additionally, vixarelimab has a first-in-class mechanism of action with the potential to positively impact the lives of patients with chronic pruritic diseases. We are executing on our clinical timelines and continue to expect data from rilonacept, mavrilimumab and KPL-404 in the second half of the year."

Mavrilimumab Treatment Protocol in COVID-19 Pneumonia and Hyperinflammation

The mavrilimumab open-label treatment protocol was a prospective, interventional, single-active-arm, single-center pilot experience in Italy[1]. Thirteen non-mechanically ventilated patients with severe COVID-19 pneumonia and hyperinflammation were treated with a single intravenous dose of mavrilimumab upon admission to the hospital. Twenty-six contemporaneous non-mechanically ventilated patients with severe COVID-19 pneumonia and hyperinflammation and with similar characteristics upon admission to the hospital, including comorbidities, baseline inflammatory markers and respiratory dysfunction, were evaluated as a control group. All patients in the treatment protocol received optimum local standard of care, including protease inhibitors and antiviral therapies.

Over the course of the 14-day follow-up period, mavrilimumab-treated patients experienced greater and earlier clinical improvements than control-group patients, including earlier weaning from supplemental oxygen, shorter hospitalizations, and no deaths.

- At day 14 of the follow-up period, 85% (n=11/13) of mavrilimumab-treated patients and 42% (n=11/26) of control-group patients had attained the clinical improvement endpoint (defined as improvement of ≥ 2 categories on a 7-point scale for assessment of clinical status) (p=0.017).
- Mavrilimumab-treated patients reached the clinical improvement endpoint earlier compared to control-group patients (median [95% CI]: 8.0 [5.0–11.0] days vs. NE (not estimable) [11.0–NE], p=0.001).
- During the 14-day follow-up period, there was a 0% (n=0) incidence of death in mavrilimumab-treated patients compared to 27% (n=7) in control-group patients (p=0.046 for time to death).
- Eight percent (n=1) of mavrilimumab-treated patients received mechanical ventilation, compared to 35% (n=9) of control-group patients (p=0.077 for time to mechanical ventilation or death).
- Mavrilimumab-treated patients were discharged from the hospital earlier than control-group patients (median [95% CI]: 10.0 [9.0–12.0] days vs. NE [12.0–NE], p=0.013).

Mavrilimumab was well-tolerated in all patients, without infusion reactions. P-values above are unadjusted for multiplicity.

Kiniksa is engaged with the U.S. Food and Drug Administration (FDA) and is preparing for a potential registrational development program for mavrilimumab in COVID-19 pneumonia and hyperinflammation. In parallel, academic investigators in the U.S. and Italy are planning investigator-initiated placebo-controlled studies.

Phase 2 Clinical Trial of Vixarelimab in Diseases Characterized by Chronic Pruritus

The exploratory Phase 2 trial in diseases characterized by chronic pruritus enrolled patients experiencing moderate-to-severe pruritus and assigned them to one of the following cohorts based upon their diagnosis: plaque psoriasis, chronic idiopathic pruritus, lichen simplex chronicus, chronic idiopathic urticaria, or lichen planus. Each cohort was evaluated as an independently randomized sub-study. Patients received a loading dose of vixarelimab 720 mg or placebo subcutaneously (SC) followed by vixarelimab 360 mg or placebo SC weekly for 8 weeks. The primary efficacy endpoint was percent change from baseline in weekly-average WI-NRS at Week 8.

- The plaque psoriasis cohort achieved a statistically significant reduction in weekly-average WI-NRS at Week 8. Least squares (LS)-mean change from baseline (mean WI-NRS score of 8.4) in weekly-average WI-NRS at Week 8 was -66.5% (n=14) in vixarelimab recipients compared to -29.0% (n=7) in placebo recipients (LS-mean difference -37.5%; p=0.012).

- In the chronic idiopathic pruritus cohort, the LS-mean change from baseline (mean WI-NRS score of 8.1) in weekly-average WI-NRS at Week 8 was -52.4% (n=14) in vixarelimab recipients compared to -48.8% (n=9) in placebo recipients (LS-mean difference -3.6%; p=0.813).

- The lichen simplex chronicus (n=4), chronic idiopathic urticaria (n=4) and lichen planus (n=3) cohorts showed encouraging efficacy results as measured by percent change from baseline in weekly-average WI-NRS at Week 8. Comparative summary statistics were not performed due to the small number of patients enrolled in each cohort.

Vixarelimab was well-tolerated, and no dose-limiting adverse events were recorded.

Kiniksa is conducting additional responder and biomarker analyses across indications to help determine next steps, including a potential dose-ranging Phase 2b trial.

The data presentations from the open-label treatment protocol of mavrilimumab in COVID-19 pneumonia and hyperinflammation and the exploratory Phase 2 trial of vixarelimab in diseases characterized by chronic pruritus are available through the Investors and Media section of Kiniksa's website (www.investors.kiniksa.com).

[1] The treatment protocol with the investigational drug mavrilimumab was conducted by Professor Lorenzo Dagna, MD, FACP, Head, Unit of Immunology, Rheumatology, Allergy and Rare Diseases IRCCS San Raffaele Scientific Institute and Vita-Salute San Raffaele University in Milan, Italy within a COVID-19 Program directed by Professor Alberto Zangrillo, Head of Department of Anesthesia and Intensive Care of the Scientific Institute San Raffaele Hospital and Università Vita-Salute San Raffaele in Milan, Italy.

About Kiniksa
Kiniksa is a biopharmaceutical company focused on discovering, acquiring, developing, and commercializing therapeutic medicines for patients suffering from debilitating diseases with significant unmet medical need. Kiniksa's clinical-stage product candidates, rilonacept, mavrilimumab, vixarelimab and KPL-404, are based on strong biologic rationale or validated mechanisms, target underserved conditions, and offer the potential for differentiation. These pipeline assets are designed to modulate immunological signaling pathways that are implicated across a spectrum of diseases. For more information, please visit www.kiniksa.com.

About Mavrilimumab
Mavrilimumab is an investigational fully-human monoclonal antibody that is designed to antagonize granulocyte macrophage colony stimulating factor (GM-CSF) signaling by binding to the alpha subunit of the GM-CSF receptor. Kiniksa's lead indication for mavrilimumab is giant cell arteritis (GCA), an inflammatory disease of medium-to-large arteries. Mavrilimumab was dosed in over 550 patients with rheumatoid arthritis through Phase 2b clinical studies in Europe and achieved prospectively-defined primary endpoints of efficacy and safety. Additionally, Kiniksa and Kite have a clinical collaboration to evaluate mavrilimumab in combination with Yescarta® (axicabtagene ciloleucel) in patients with relapsed or refractory large B-cell lymphoma.

About the Mavrilimumab Treatment Protocol in COVID-19 Pneumonia & Hyperinflammation
The mavrilimumab open-label treatment protocol was a prospective, interventional, single-active-arm, single-center pilot experience in Italy. Patients suffering from severe pulmonary involvement of COVID-19, acute respiratory distress, fever, and clinical and biological markers of systemic hyperinflammation status were treated with a single intravenous dose of mavrilimumab. The objective of the treatment protocol was to determine whether mavrilimumab in addition to standard management could improve clinical outcomes in patients with COVID-19 pneumonia and hyperinflammation. A control-group was assembled consisting of contemporaneous patients receiving local standard of care and matched for age, sex, comorbidities, baseline inflammatory markers and respiratory dysfunction. Per standard of care of the hospital, all patients received on admission medical treatment with hydroxychloroquine, azithromycin, and lopinavir/ritonavir as well as respiratory support with supplemental oxygen and/or non-invasive ventilation with continuous positive airway pressure.

About Vixarelimab
Vixarelimab is an investigational fully-human monoclonal antibody that targets OSMRβ, which mediates signaling of interleukin-31 (IL-31) and oncostatin M (OSM), two key cytokines implicated in pruritus, inflammation and fibrosis. Kiniksa believes vixarelimab to be the only monoclonal antibody in development that targets both pathways simultaneously.

About the Vixarelimab Phase 2 Trial in Diseases Characterized by Chronic Pruritus
The Phase 2 trial was a randomized, double-blind, placebo-controlled pilot study designed to investigate the efficacy, safety, and tolerability of vixarelimab in reducing pruritus in diseases characterized by chronic pruritus. The trial enrolled patients with chronic idiopathic urticaria, chronic idiopathic pruritus, lichen planus, lichen simplex chronicus or plaque psoriasis experiencing moderate-to-severe pruritus (WI-NRS ≥ 7 at the screening visit and a mean weekly WI-NRS of ≥ 5 at Day 1 of the treatment period). Patients were required to stop antihistamines and topical treatments, including corticosteroids, for at least two weeks prior to dosing. Treatments for these diseases characterized by chronic pruritus, other than study drug, were not allowed except for rescue. For more information, refer to ClinicalTrials.gov Identifier: NCT03858634.

Forward-Looking Statements

The information contained in this press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. In some cases, you can identify forward looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplate,” “believe,” “estimate,” “predict,” “potential” or “continue” or the negative of these terms or other similar expressions, although not all forward-looking statements contain these identifying words. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation, statements regarding the outcomes across our product candidate pipelines to-date; the potential broad utility of mavrilimumab; the potential impact and differentiation of the OSMRβ mechanism; our potential registrational development program and investigator initiated studies for mavrilimumab in COVID-19 pneumonia and hyperinflammation; our clinical collaboration with Kite in CAR T cytokine storm; the potential for vixarelimab to positively impact the lives of patients with chronic pruritic diseases, including prurigo nodularis; timing of data from our product candidates; potential impact of data from our product candidates on our portfolio strategy and capital allocation; and the potential for all of our clinical stage product candidates to offer differentiation.

These forward-looking statements are based on management’s current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including without limitation, the following: the potential for changes between final or a broader set of data and any “top-line,” interim and preliminary data we announce; the impact of additional data from us or other companies; the potential inability to replicate in later clinical trials positive results from our earlier clinical trials or investigator initiated treatment protocols for our product candidates; the potential for undesirable side effects to be caused by our product candidates; our reliance on third parties to manufacture our product candidates and conduct our clinical trials; the potential impact of the COVID-19 pandemic and measures taken in response to the pandemic; changes in our operating plan and funding requirements; existing or new competition; and our ability to attract and retain qualified personnel.

These and other important factors discussed under the caption “Risk Factors” in our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (“SEC”) on May 4, 2020 and our other reports subsequently filed with or furnished to the SEC could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management’s estimates as of the date of this press release. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

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