Adagene Presents Data Demonstrating First and Best-in-Class Potential for Differentiated Preclinical Antibody Candidates at American Association for Cancer Research (AACR) Annual Meeting 2022

April 8, 2022

- Poster presentations showcase SAFEbody® precision masking technology applicability across targets and modalities –

- IND or equivalent filings planned for two new product candidates in 2022, including masked anti-CD137 antibody with Fc engineering and masked anti-CD47 antibody, designed to enhance both safety and efficacy -

SAN DIEGO and SUZHOU, China, April 08, 2022 (GLOBE NEWSWIRE) -- Adagene Inc. ("Adagene") (Nasdaq: ADAG), a company transforming the discovery and development of novel antibody-based therapies, today announced preclinical data showcasing the potential first and best-in-class profile of new antibody candidates. Data are being presented at the American Association for Cancer Research (AACR) Annual Meeting, taking place in New Orleans, Louisiana from April 8-13, 2022. Posters are available in the Publications section of the company's website at www.adagene.com.

"We are encouraged by the preclinical data presented across four posters at AACR, showing the first and best-in-class profiles for our differentiated preclinical candidates, designed to achieve safe, potent and durable responses. These include ADG206, a masked, IgG1 Fc-engineered anti-CD137 therapy and ADG153, a masked anti-CD47 IgG1 antibody, and ADG138, a novel, double masked HER2xCD3 bispecific T-cell engager (TCE) for solid tumors. All three of these candidates are designed for improved efficacy while incorporating precision masking peptides to ensure safety of such powerful modalities," said Peter Luo, Ph.D., Co-founder, Chief Executive Officer and Chairman of Adagene. "Additionally, we are establishing a new paradigm for CD28 TCEs by targeting a unique, highly conserved epitope for local activation, and leveraging SAFEbody to ensure ultimate safety and mitigate known risks of this target. We are very excited to show potential differentiation of these preclinical candidates, and spotlight our ability to create first/best-in-class product candidates that can be safely and effectively combined together as we aspire to cure cancer."

Key takeaways from the four posters include:

ADG206, an anti-CD137 agonistic POWERbody™ with tailor-made efficacy and safety profiles by strong crosslinking and tumor selective activation for single agent and combinational cancer immunotherapy *(#2868)*

- This masked, IgG1 Fc-engineered anti-CD137 POWERbody combines conditional activation in the tumor microenvironment with strong agonistic activity through heightened FcγR-mediated crosslinking for therapeutic potential in either single agent or combination regimens.
- Preclinical data demonstrated that ADG206 was well tolerated and had robust anti-tumor activity as a single agent in multiple tumor models, with 4-fold stronger anti-CD137 agonistic activity of its activated form than a benchmark antibody in development (analog of urelumab) for T cell co-activation.
- ADG206 also demonstrated enhanced anti-tumor activity in combination with other checkpoint inhibitors, including anti-PD-1 or anti-CTLA-4 therapy.
- Adagene is preparing to submit an IND or equivalent filing for ADG206 during 2022.

ADG153-G1 SAFEbody, a differentiated masked anti-CD47 antibody of IgG1 subclass, demonstrates in vivo anti-tumor activity consistent with enhanced ADCC/ADCP effects and significantly reduced RBC-related and antigen sink liabilities *(#4257)*

- This masked anti-CD47 IgG1 SAFEbody is differentiated by its strong antibody-dependent cellular cytotoxicity (ADCC) and antibody-dependent cellular phagocytosis (ADCP) activity designed to realize the full potential of anti-CD47 therapy for both hematologic and solid tumor indications.
- Preclinical data demonstrated that ADG153 IgG1 was well tolerated, did not induce human hemagglutination and significantly reduced anemia-related and antigen sink liabilities. In particular, ADG153 IgG1 at a 10 mg/kg dose demonstrated only an 8 percent decrease in red blood cell counts, compared to a 49 percent decrease with a benchmark antibody which is in IgG4 format (analogue of magrolimab).
- Results also showed that ADG153 IgG1 demonstrated greater anti-tumor activity than the benchmark.
- Adagene is preparing to submit an IND or equivalent filing for ADG153 during 2022.

ADG138, A Novel HER2×CD3 POWERbody™ Integrating Bispecific TCE with Precision Masking to Control Cytokine Release Syndrome and On-Target Off-Tumor Toxicity for Single Agent and Combination Therapies in HER2-Expressing Solid Tumors *(#2869)*

- This novel HER2xCD3 POWERbody is masked on both arms with an impressively high therapeutic index relative to its parental non-masked TCE in both HER2 high and low expressing solid tumors, supporting its development for HER2-expressing solid tumors as a single agent and in combination with other immune modulating agents.
- Preclinical data demonstrated the excellent safety profile of ADG138, including 100-fold greater reduction in cytokine release compared to its parental TCE.

- Results showed that ADG138 has potent anti-tumor activity in HER2 high and low expressing tumors, as well as resistant/refractory tumors, relative to a benchmark antibody (DS-8201, a HER2 targeting antibody drug conjugate commercially available in specific indications). ADG138 also had synergistic anti-tumor activity in HER2 positive tumors when combined with anti-CD137 or anti-PD-1 therapy, or tumor targeted CD28 bispecific antibody.
- ADG138 is currently in IND-enabling studies.

Tumor-targeted CD28 bispecific POWERbody™ for safe and synergistic T cell-mediated immunotherapy *(#2888)*

- CD28 bispecific POWERbody TCEs exhibit enormous potential to fulfill the promises of safe and durable T cell-mediated synergistic immunotherapies when combined with CD3 bispecific POWERbody TCEs and/or checkpoint inhibitors.
- Enabled by Adagene's suite of antibody platform technologies, preclinical data demonstrated the potential to mitigate the serious safety concerns of CD28 activation and make custom designed antibodies targeting a highly conserved epitope with broad species reactivity.
- Multiple tumor associated antigen (TAA)xCD28 POWERbodies are in progress, such as B7-H3xCD28 and HER2xCD28, which can also be combined with the company's CD3 TCEs to achieve safe, powerful and durable immunotherapy for solid tumors through combination of the fundamental mechanisms and pathways across the cancer immunity cycle.

About Adagene
Adagene Inc. (Nasdaq: ADAG) is a platform-driven, clinical-stage biopharmaceutical company committed to transforming the discovery and development of novel antibody-based cancer immunotherapies. Adagene combines computational biology and artificial intelligence to design novel antibodies that address unmet patient needs. Powered by its proprietary Dynamic Precision Library (DPL) platform, composed of NEObody™, SAFEbody®, and POWERbody™ technologies, Adagene's highly differentiated pipeline features novel immunotherapy programs.Adagene has forged strategic collaborations with reputable global partners that leverage its technology in multiple approaches at the vanguard of science.

For more information, please visit: https://investor.adagene.com. Follow Adagene on WeChat, LinkedIn and Twitter.

SAFEbody® is a registered trademark in the United States, China, Australia, Japan, Singapore, and the European Union.

Safe Harbor Statement
This press release contains forward-looking statements, including statements regarding the preclinical studies of ADG138, ADG206, ADG153 and a tumor-targeted CD28 bispecific POWERbody™, the potential implications of preclinical findings of these product candidates, and Adagene's advancement of, and anticipated clinical development, regulatory milestones and commercialization of Adagene pipeline candidates. Actual results may differ materially from those indicated in the forward-looking statements as a result of various important factors, including but not limited to Adagene's ability to demonstrate the safety and efficacy of its drug candidates; the clinical results for its drug candidates, which may not support further development or regulatory approval; the content and timing of decisions made by the relevant regulatory authorities regarding regulatory approval of Adagene's drug candidates; Adagene's ability to achieve commercial success for its drug candidates, if approved; Adagene's ability to obtain and maintain protection of intellectual property for its technology and drugs; Adagene's reliance on third parties to conduct drug development, manufacturing and other services; Adagene's limited operating history and Adagene's ability to obtain additional funding for operations and to complete the development and commercialization of its drug candidates; Adagene's ability to enter into additional collaboration agreements beyond its existing strategic partnerships or collaborations, and the impact of the COVID-19 pandemic on Adagene's clinical development, commercial and other operations, as well as those risks more fully discussed in the "Risk Factors" section in Adagene's filings with the U.S. Securities and Exchange Commission. All forward-looking statements are based on information currently available to Adagene, and Adagene undertakes no obligation to publicly update or revise any forward looking statements, whether as a result of new information, future events or otherwise, except as may be required by law.

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