# Cyclacel Pharmaceuticals Announces Preclinical Proof-of-Concept Data for Fadraciclib to be Presented at the American Association for Cancer Research (AACR) Annual Meeting 2024

March 7, 2024

**Data support ongoing development program of novel CDK2/9 inhibitor fadraciclib in patients with solid tumors and lymphoma**

BERKELEY HEIGHTS, N.J., March 07, 2024 (GLOBE NEWSWIRE) -- Cyclacel Pharmaceuticals, Inc. (NASDAQ: CYCC, NASDAQ: CYCCP; "Cyclacel" or the "Company"), a biopharmaceutical company developing innovative medicines based on cancer cell biology, today announced that preclinical proof-of-concept data with the Company's fadraciclib will be presented at the upcoming American Association for Cancer Research (AACR) Annual Meeting 2024, being held April 5-10 in San Diego, California. The data will be presented at three poster sessions and report activity and antitumor effects of fadraciclib in biliary tract cancer, lung cancer, Richter transformation and lymphoma cell lines.

Details of the presentations are as follows:

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| **Title:** | The CDK2/9 inhibitor fadraciclib is active in Richter transformation and lymphoma cell lines by targeting both cell survival and proliferation |
| **Abstract No:** | 518 / 15 |
| **Session Topic:** | Session PO.ET05.01 - Cell Cycle, Transcription Regulation, and Anticancer Drug Action |
| **Date and Time:** | April 7, 2024, 1:30 PM - 5:00 PM PT |
| **Location:** | Exhibition Hall, Section 21 |

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| **Title:** | Elucidation of the fates of CDK2 inhibited aneuploid and residual lung cancers |
| **Abstract No:** | 2117 / 8 |
| **Session Topic:** | Session PO.ET07.02 - Pharmacodynamic Biomarkers of Drug Response |
| **Date and Time:** | April 8, 2024, 9:00 AM - 12:30 PM PT |
| **Location:** | Exhibition Hall, Section 30 |

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| **Title:** | Anti-tumor effects of fadraciclib, CDK2/9 inhibitor, in biliary tract cancer |
| **Abstract No:** | 5711 / 11 |
| **Session Topic:** | Session PO.MCB01.01 - Pharmacologic Targeting of Cell Cycle Proteins |
| **Date and Time:** | April 9, 2024, 1:30 PM - 5:00 PM PT |
| **Location:** | Exhibition Hall, Section 18 |

**About Cyclin-Dependent Kinases and Fadraciclib**
Cyclin-dependent kinases (CDKs) are critical for cell cycle control and transcriptional regulation. Dysregulated CDKs have been linked to the cancer hallmarks of uncontrolled proliferation and increased cancer cell survival. Fadraciclib is a highly selective, potent, orally and intravenously available, next generation inhibitor of CDK2 and CDK9. By inhibiting CDK2 and CDK9 fadraciclib causes apoptotic death through anaphase catastrophe of cancer cells at sub-micromolar concentrations.

To date single agent activity, including CR, PR and SD, has been observed in patients with advanced endometrial, squamous NSCLC lung cancer and T-cell lymphoma. Encouraging signals of activity were observed in patients with advanced cervical, hepatocellular, ovarian and pancreatic cancers.

**065-101 Study of Oral Fadraciclib**

Oral fadraciclib is being tested in a Phase 1/2 trial for the treatment of advanced solid tumors and lymphoma (065-101; NCT#04983810). A total of 29 patients have been treated as monotherapy in this ongoing study. The study is enrolling unselected, all comer patients with advanced solid tumors and lymphoma.

The Phase 2 part of the 065-101 study is designed to further evaluate fadra safety and efficacy in up to 8 cohorts defined by histology and/or NGS. The study is powered to demonstrate response in the molecular subtype suggested by the Phase 1 data and others that may be sensitive.

**CDKN2A, CDKN2B, MTAP deletions**

CDKN2A gene deletions occur in over 40% of several solid tumors, including glioma, head and neck, pancreatic, esophageal, lung (incl. squamous), bladder, melanoma, and others. CDKN2B deletions occur in over 30% of several solid tumors, including bladder, glioma, pancreatic, esophageal, lung (incl. squamous), head and neck, melanoma, and others. MTAP deletions occur in over 25% of several solid tumors, including glioma, mesothelioma, pancreatic, bladder, esophageal and others. MTAP deletion confers dependency on the PRMT5 enzyme in cancer cells which was identified as a

synthetic lethal target for MTAP deleted cancers.

**About Cyclacel Pharmaceuticals, Inc.**

Cyclacel is a clinical-stage, biopharmaceutical company developing innovative cancer medicines based on cell cycle, transcriptional regulation and mitosis biology. The transcriptional regulation program is evaluating fadraciclib, a CDK2/9 inhibitor, and the anti-mitotic program CYC140, a PLK1 inhibitor, in patients with both solid tumors and hematological malignancies. Cyclacel's strategy is to build a diversified biopharmaceutical business based on a pipeline of novel drug candidates addressing oncology and hematology indications. For additional information, please visit www.cyclacel.com.

**Forward-looking Statements**

This news release contains certain forward-looking statements that involve risks and uncertainties that could cause actual results to be materially different from historical results or from any future results expressed or implied by such forward-looking statements. Such forward-looking statements include statements regarding, among other things, the efficacy, safety and intended utilization of Cyclacel's product candidates, the conduct and results of future clinical trials, plans regarding regulatory filings, future research and clinical trials and plans regarding partnering activities. Factors that may cause actual results to differ materially include the risk that product candidates that appeared promising in early research and clinical trials do not demonstrate safety and/or efficacy in larger-scale or later clinical trials, trials may have difficulty enrolling, Cyclacel may not obtain approval to market its product candidates, the risks associated with reliance on outside financing to meet capital requirements, the potential effects of the COVID-19 pandemic, and the risks associated with reliance on collaborative partners for further clinical trials, development and commercialization of product candidates. You are urged to consider statements that include the words "may," "will," "would," "could," "should," "believes," "estimates," "projects," "potential," "expects," "plans," "anticipates," "intends," "continues," "forecast," "designed," "goal," or the negative of those words or other comparable words to be uncertain and forward-looking. For a further list and description of the risks and uncertainties the Company faces, please refer to our most recent Annual Report on Form 10-K and other periodic and other filings we file with the Securities and Exchange Commission and are available at www.sec.gov. Such forward-looking statements are current only as of the date they are made, and we assume no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

**Contacts**


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