Ellipses Pharma
ellipses.life

ELL:PSES™ PHARMA

Ellipses Pharma—distilling cancer drug development to its essence

Ellipses Pharma has implemented a disruptive approach to cancer drug development that greatly accelerates the delivery of novel solutions for patients. With seven lead products and a growing pipeline of assets, the company is planning to have a first drug ready for out-licensing in 2024.

Ellipses Pharma, a global drug development company based in London, focuses on accelerating the development of cancer medicines and treatments through an innovative drug development model that combines unbiased vetting to de-risk initial asset selection with an uninterrupted funding flow to minimize the time it takes to advance lead products through clinical trials and reach patients (Fig. 1).

Ellipses—from the Ancient Greek ἔλλειψις (élleipsis: leave out)—distills the cancer drug development process to its essential components by removing hurdles such as rounds of capital raising or suboptimal clinical trial outcomes that typically delay, or worse, stall drug development. Keeping a sharp focus on out-license requirements, including regulatory frameworks and individual patient needs, provides a natural roadmap.

"At Ellipses we believe that, in a way, to beat cancer we need to think like cancer—we need to constantly evolve, continually multiply and rapidly accelerate," said Rajan Jethwa, CEO and founder of Ellipses. "We have designed our business model around these principles to maximize the breakthrough potential of the opportunities we take on, streamline their path through the clinic, and shorten the time for them to have an impact on patients."

Since becoming operational in 2018, Ellipses has accrued a pipeline encompassing seven in-licensed assets, with two ongoing clinical trials and five more to start in 2022 from the first half, several assets in due diligence, and close to 200 other assets in exploratory evaluation. With a continuously expanding pipeline and first assets slated for out-licensing in 2024, Ellipses is rapidly turning its disruptive drug development proposition into a new and tangible reality.

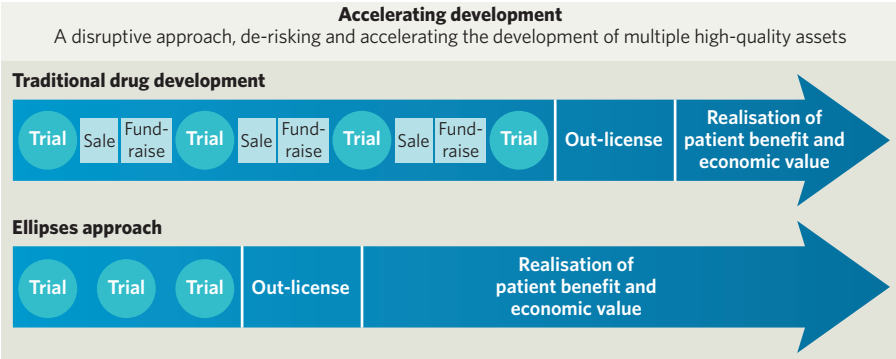

Fig. 1 | The Ellipses drug development model. Capitalizing on a strategy of uninterrupted financing, Ellipses achieves quicker trial completion, leading to lower cost of development, increased asset value, speedier commercialization, and most importantly, earlier patient benefit.

De-risking asset selection

Arguably the most important decision affecting the success of a drug development program is the initial step of evaluating both the true therapeutic and translational potentials of a novel discovery. Ellipses has introduced a blind review process that eliminates group-think and potential institutional biases by crowdsourcing the evaluation to a global network of oncology experts. With more than 120 scientists and clinicians from Europe, the Americas and the Asia-Pacific region, this unique-in-its-kind scientific affairs group (SAG) covers a broad range of cancer specialties. The SAG is singularly focused on identifying the science with the clearest path toward translation into clinical application.

> **"Our mission at Ellipses is to make the very best drugs and therapies available, at unprecedented speed, to patients worldwide"**
>
> Christopher Evans, chairman and founder, Ellipses

Specifically, the SAG is charged with providing clinically relevant input on the science, indications and patient needs for each asset. The assets identified by the SAG typically range from preclinical to phase 2 clinical stage assets, and the independent scientific and clinical consensus articulated by the SAG provides Ellipses with invaluable information to ensure it designs and runs the right trials, in the right patients, and at the right time to efficiently advance the assets to the out-licensing stage. A core group of the SAG remains engaged with Ellipses' business and clinical development groups to ensure quality parameters are maintained throughout the development program and goals are adjusted as necessary.

"Our mission at Ellipses is to make the very best drugs and therapies available, at unprecedented speed, to patients worldwide," said Christopher Evans, chairman and founder of Ellipses. "And to achieve this goal, we seek out those scientific discoveries with the best chances of success, regardless of tumor type, development stage, molecular target, or therapeutic modality."

Uninterrupted drug development

Once Ellipses in-licenses an asset, both the clinical and business development programs for the asset are jointly built around both high quality clinical trials focused on patient needs and the commercial requirements for out-licensing. The key to accelerating the process is Ellipses' permanent fixed source of funding, which allows the company to allocate capital to an asset as soon as it is needed and without having to wait for a specific fundraising round. As a result, Ellipses has the ability to design novel and effective omics-driven and stratified clinical trials that boost response rates, optimize regulatory compliance, and maximize commercial potential. Added value is provided by Ellipses' agile patient recruitment strategies alongside active direct management of clinical trials that help achieve time and cost efficiencies and minimize value erosion.

"We have built a streamlined drug development engine that scales with asset acquisition, ensuring we are always ready to run high-quality trials at the right time for all assets," said Jethwa. "By decoupling our fundraising from the asset development cycle, we can provide uninterrupted financial support for each development program as required by individual program needs and timelines."

A robust and diverse pipeline

Ellipses' drug development model was designed with an eye to maximizing the out-licensing potential of its portfolio. A key ingredient for achieving this goal is to build a robust—from late preclinical to clinical stage—and diverse—from solid tumors to blood cancers—pipeline in which the sum of the assets provides a synergistic advantage over the intrinsic value of each individual asset. By diversifying the risk, Ellipses can optimize the use of the company's development engine, accelerating execution of individual assets, limiting overall operational risk and maximizing value capture.

Ellipses' inaugural cohort, consisting of seven drug development programs and several more assets undergoing due diligence prior to in-licensing, exemplifies this strategy: the pipeline addresses more than a dozen different types of cancers—including acute myeloid leukemia (AML), glioblastoma, breast cancer, lung cancer and other solid tumors—with assets in development stages ranging from preclinical/pre-investigational new drug (IND) to phase 2 clinical studies and encompassing several therapeutic modalities, including anti hormonal agents, tyrosine kinase inhibitors, peptide prodrugs, small molecule modulators, functionalized nanoparticles and antibodies (Fig. 2).

- ***EP0057—nanoparticle drug conjugate for the treatment of advanced ovarian cancer.*** EP0057, acquired from a US public company, is a potential first-in-class nanoparticle functionalized with the topoisomerase 1 inhibitor camptothecin under investigation for the treatment of platinum-resistant and platinum-sensitive advanced ovarian cancer in combination with olaparib, a polyadenosine diphosphate-ribose polymerase inhibitor (PARPi). An adaptive phase 2 study is in progress with phase 2a cohorts currently recruiting in the USA and Europe that will inform progression to a planned randomized phase 2b proof-of-concept study. EP0057 has orphan drug designation in advanced ovarian cancer.

  Ellipses is exploring additional indications, including advanced ataxia telangiectasia mutated (ATM)–negative gastric cancer and small cell lung cancer (SCLC), with signal searching phase 2 studies in both types of cancer launching in the first half of 2022 at sites in China, Taiwan, and South Korea.
- ***EP0042—next generation dual tyrosine kinase inhibitor for the treatment of acute myeloid leukemia.*** EP0042, discovered at The Institute of Cancer Research, London with support from Cancer Research UK, is a potential first-in-class dual inhibitor of FMS-like tyrosine kinase 3 (FLT3) and aurora kinases A and B (AUKA/AUKB) under investigation for the treatment of AML. A phase 1 dose ranging study is in progress in anticipation of studying EP0042 in combination with a B cell lymphoma-2 (BCL-2) inhibitor, and a hypomethylating agent in patients with AML.
- ***EP0062—hormone receptor modulator for the treatment of advanced breast cancer.*** EP0062, in-licensed from a US biotech company, is a potential best-in-class selective androgen receptor modulator (SARM) that is under investigation for the treatment of estrogen receptor-α (ER) + / human epidermal growth factor receptor 2 (HER2) - / androgen receptor (AR) + (ER+/HER2-/AR+) advanced breast cancer (ABC). Encouraging preliminary phase 1 data have been recently published for this agent[1]. Phase 1 assessment of this agent will continue in 2022 with evaluation of an improved formulation of EP0062 as a monotherapy in ER+/HER2-/AR+ ABC patients. This trial will inform progression to phase 2 studies that will evaluate EP0062 in combination with current standard-of-care regimens in ER+/HER2-/AR+ ABC patients.
- ***EP0031—next generation selective RET inhibitor for the treatment of solid tumors.*** EP0031, in-licensed from a US/China pharma company, is a potential best-in-class next generation selective RET (rearranged during transfection) inhibitor (SRI) under investigation for the treatment of RET aberration positive solid tumors. A phase 1 study is planned to launch in 2022 to evaluate EP0031 in patients with first generation SRI resistant and naive thyroid cancer and other solid tumors. EP0031 has the potential for orphan drug designation in RET aberration positive solid tumors.

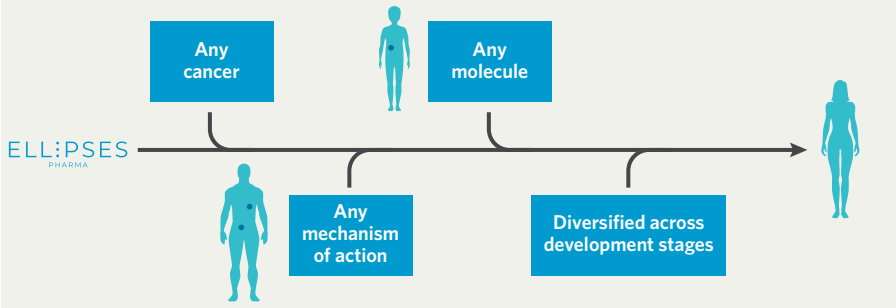

Fig. 2 | Ellipses' pipeline—creating value through enhanced diversification and risk management. A robust and diverse pipeline allows Ellipses to optimize the use of its development engine, accelerating execution, limiting operational risk and maximizing value capture for each individual asset.

> **"We have built a streamlined drug development engine that scales with asset acquisition, ensuring we are always ready to run high-quality trials at the right time for all assets**
>
> Rajan Jethwa, CEO and founder, Ellipses

- ***EP0023—targeted peptide theranostic for the treatment of glioblastoma.*** EP0023, in-licensed from a US university, is a potential first-in-class matrix metalloproteinase 14 (MMP14)–targeted peptide theranostic prodrug under investigation for the treatment of glioblastoma and other MMP14-expressing tumors. Ellipses is performing CMC (chemistry, manufacturing, and controls), formulation, and IND-enabling studies on EP0023. EP0023 has the potential for orphan drug designation in multiple MMP14-expressing cancers.
- ***EP0058—nanoparticle drug conjugate for the treatment of NSCLC.*** EP0058, acquired from a US public company, is a potential first-in-class nanoparticle functionalized with docetaxel in preclinical development for the treatment of NSCLC and other solid tumors with progression to clinical development being de-risked following positive clinical outcomes from the ongoing EP0057 phase 2 clinical trial.
- ***EP0015—targeted peptide for the treatment of solid tumors.*** EP0015, acquired from a UK biotech company, is a potential first-in-class targeted peptide prodrug under evaluation for the treatment of solid tumors. Ellipses is performing CMC, formulation, and IND-enabling studies on EP0015 in preparation for a first-in-human monotherapy basket study in solid tumors.

Additional exploratory programs in Ellipses' pipeline include several bispecific, bifunctional, and monoclonal antibodies to treat a range of relapsed or refractory tumors following immunotherapy, EGFR-resistant cancers, and triple-negative breast cancer.

Ellipses is accelerating the pace of expansion of its pipeline over the next few years and projects its first programs to be ready for out-licensing in 2024.

"Traditional drug development models have failed to keep pace with the speed and scale of cancer, so at Ellipses we decided to adopt a bold and ambitious approach that limits operational risk and maximizes outcomes for patients," said Jethwa. "We are now poised to continue growing our portfolio and through it contribute to accelerating the development of the very best innovative cancer medicines and treatments."

1. LoRusso, P. et al. *Clin. Breast Cancer* **22**, 67–77 (2022).

CONTACT
Rajan Jethwa, CEO & founder
Ellipses Pharma
London, UK
Tel:+44 20 3743 0992
Email: media@ellipses.life