Intelligencia AI

September: Ovarian Cancer Awareness Month

As September marks ovarian cancer awareness month, we studied our data at Intelligencia AI to better understand this disease's current and potential future state of drug development.

Globally, ovarian cancer is one of the leading causes of cancer deaths among women and is the fifth leading cause in the U.S.[1]

When ovarian cancer first develops, it might not display any noticeable symptoms. Even when symptoms are noticed, they are usually attributed to other, more common indications (e.g., abdominal bloating, constipation, weight loss).

The most common type of ovarian cancer is Epithelial ovarian cancer (90-95%)[2]. It can be further classified under five possible histotypes: high-grade serous, low-grade serous, endometrioid, clear cell and mucinous carcinomas[3].

Reported global ovarian cancer incidence is about 6.7 per 100,000 person-years.[3] It has a relative 5-year survival rate of 50.8%[4].

HOW IS OVARIAN CANCER CURRENTLY TREATED?

Commonly used types of treatment[5]:

- **Surgery**
- **Radiation therapy**
- **Chemotherapy**
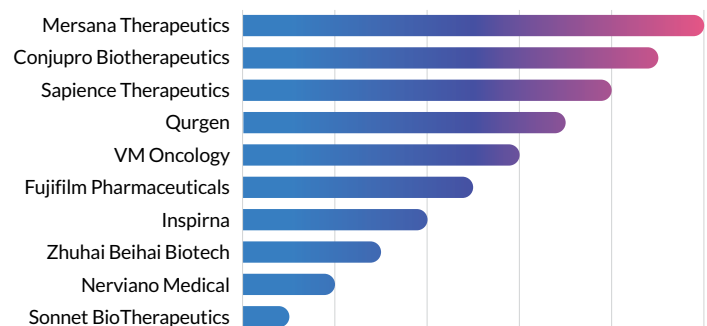- **Hormone therapy**
- **Targeted therapy**
- **Immunotherapy**

In the past five years, the following drugs have received regulatory approval by the FDA: Olaparib, Niraparib and Mirvetuximab Soravtansine. Olaparib and Niraparib are both small molecule inhibitors targeting Poly (Adenosine Diphosphate-Ribose) Polymerase (PARP). Mirvetuximab Soravtansine is an antibody-drug conjugate (ADC) targeting Folate receptor alpha.

DETAILS IN THE DATA: HERE'S WHAT WE LEARNED ABOUT OVARIAN CANCER AWARENESS MONTH

**In analyzing our data[6], we identified:**

- 355 **ongoing** industry-led, FDA-track interventional clinical development programs* among which:
    - *121 are in Phase 1 or 1b,*
    - *197 are in Phase 2 or 1/2 and*
    - *37 are in Phase 2/3 or Phase 3.*

- The programs mentioned above are conducted by 188 different primary sponsors and correspond to 326 investigational drugs/drug combinations, covering 96 different drug modalities/modality combinations.

Top 10 Sponsors in Ovarian Cancer - Ranked by Intelligencia AI Pipeline Performance Score

Mersana Therapeutics
Conjupro Biotherapeutics
Sapience Therapeutics
Qurgen
VM Oncology
Fujifilm Pharmaceuticals
Inspirna
Zhuhai Beihai Biotech
Nerviano Medical
Sonnet BioTherapeutics

Our pipeline performance score leverages our patented AI-driven probability of technical and regulatory success (PTRS) assessments.
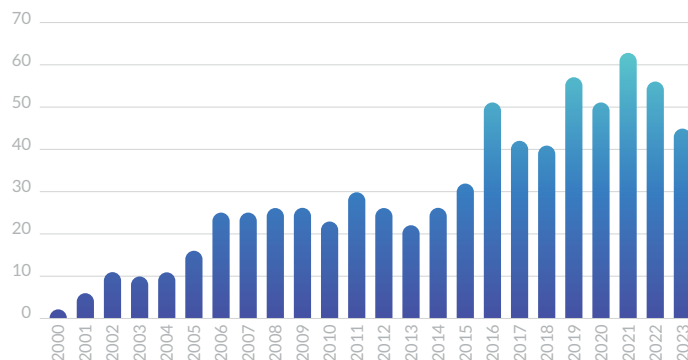
Sponsors With the Highest Number of Active Ovarian Cancer Clinical Programs
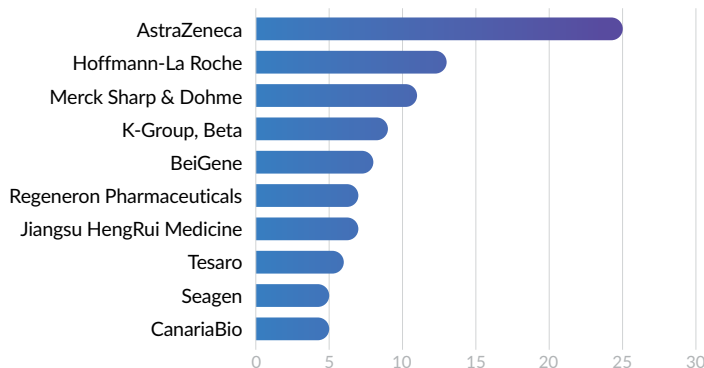
These are the top sponsors based on the number of ongoing ovarian cancer clinical programs.*

Distribution of Ovarian Cancer Clinical Programs by Year of Initiation Since 2000

While between 2006 and 2014, the number of initiated programs was relatively stable, an upward trend can be observed starting around 2016. This coincides with the establishment of targeted therapies as a new standard of care in ovarian cancer.

- Among industry-led, FDA-track historical programs, 30% transitioned from Phase 1 to Phase 2 and 3% from Phase 2 to Phase 3.

- There have been 20 drugs (run by 19 different sponsors) that have not received prior FDA approval in ovarian cancer and are being tested in Phase 3 trials.

- The majority of these 20 drugs fall under two different modalities: monoclonal antibodies (mAbs) and small-molecule inhibitors (SMIs). The exceptions are Raludotatug

deruxtecan, Luveltamab tazevibulin and SHR-A1921, which are all ADCs; Nemvaleukin Alfa, a recombinant fusion protein; and Olvimulogene nanivacirepvec, an oncolytic virus.

- In terms of Mechanism of Action (MoA), the most common target for mAbs is the Programmed cell death protein 1 (PD-1)/Programmed cell death 1 ligand 1 (PD-L1) Pathway, while the most common target for SMIs is PARP. However, there is still quite a bit of variety in the targeted molecules.

PERSPECTIVE: WHAT DOES THIS ALL MEAN?

Despite significant advances in oncology, the main treatments for ovarian cancer include surgery and chemotherapy. Taking into account the small number of recent approvals, as well as the disease's 5-year survival rate, ovarian cancer indeed constitutes an unmet need for patients. It is a need that the pharmaceutical industry seems eager to address, especially when considering the fact that almost every non-approved Phase 3 asset currently in development

is run by a different sponsor. Steps are being taken in the right direction (successful targets and modalities are being further explored, and multiple unproven targets are being tested). Still, there is an imperative need for more biomarkers to be identified, both for early detection and treatment in advanced stages. In the foreseeable future, most of the industry's focus will be on further exploration of the disease.

About Intelligencia AI

Intelligencia AI™ leads the way in leveraging proprietary data, biomedical expertise and artificial intelligence (AI) with its patented technology to address significant challenges in the pharmaceutical industry. These challenges include lengthy drug development timelines, excessive costs, and unsustainable return on investment (ROI). Its suite of AI-powered solutions delivers actionable insights crucial in mitigating risks and enhancing decision-making associated with drug development by providing an accurate, unbiased assessment of a drug's probability of success. Founded in 2017, Intelligencia AI is headquartered in New York, NY, with offices in Athens, Greece, and employs 110 individuals globally. Visit intelligencia.ai to discover more.

References

1 He J, Hu Q. Ovarian cancer disease burden decreased in the United States from 1975 to 2018: A joinpoint and age-period-cohort analysis. Medicine (Baltimore). 2023 Dec 1;102(48):e36029. doi: 10.1097/MD.0000000000036029. PMID: 38050303; PMCID: PMC10695534.

2 Arora T, Mullangi S, Vadakekut ES, et al. Epithelial Ovarian Cancer. [Updated 2024 May 6]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK567760/

3 Köbel M, Kang EY. The Evolution of Ovarian Carcinoma Subclassification. Cancers (Basel). 2022 Jan 14;14(2):416. doi: 10.3390/cancers14020416. PMID: 35053578; PMCID: PMC8774015

4 https://ocrahope.org/get-the-facts/statistics/#:~:text=The%20relative%20five%2Dyear%20survival,ovarian%20cancer%20is%2050.8%25%20percent.

5 https://www.dana-farber.org/cancer-care/types/ovarian-cancer/treatment#:~:text=Surgery%20is%20the%20main%20treatment,tumors%20and%2For%20preserve%20fertility.

6 Intelligencia AI data as of August 29, 2024

Intelligencia AI   intelligencia.ai

A program (also known as clinical pipeline or drug pipeline) is the clinical development of a drug (or a set of drugs in case of combination therapies) by a pharmaceutical company (alone or in collaboration with other partners) for an indication. A program consists of a set of clinical trials with the ultimate goal of approval for marketing. Each program has unique and specific parameters that can potentially justify a separate regulatory approval. Specifically, the definition of a clinical program is one of unique drug(s), drug dosage, mode of administration, adjuvant state, indication, sponsor, disease severity (e.g. stage of disease), line of treatment and biomarker information used as inclusion criteria.