Intelligencia AI

Cervical Cancer

We analyzed our expertly curated clinical and biological data at Intelligencia AI to generate a high-level view of the current and potential future state of drug development for cervical cancer.

While mostly asymptomatic in early stages, later symptoms include abnormal vaginal bleeding, pain during sexual intercourse and pelvic pain[1].

Almost the entirety of cervical cancer cases is linked to genital human papillomavirus (HPV) infections. This does not mean, however, that HPV infections always lead to cervical cancer[2,3].

About 90% of cervical cancer cases are squamous cell carcinomas, 10% are adenocarcinomas, with an extremely small number of cases belonging to other types[4].

HPV vaccination is the most effective measure against cervical cancer, as it protects against the family of viruses that cause this disease, and may prevent up to 90% of cervical cancer cases[5].

There is a significant discrepancy in prevalence and mortality rates when comparing low- and mid-income countries with high-income countries. Up to 88% of cervical cancers and 90% of relevant deaths occur in the former[6].

HOW IS CERVICAL CANCER CURRENTLY TREATED?

Commonly used types of treatment[7]:

- Surgery
- Radiation therapy
- Chemotherapy
- Targeted therapy
- Immunotherapy

In the past five years, only two drugs received regulatory approval from the FDA: Tivdak and Keytruda.

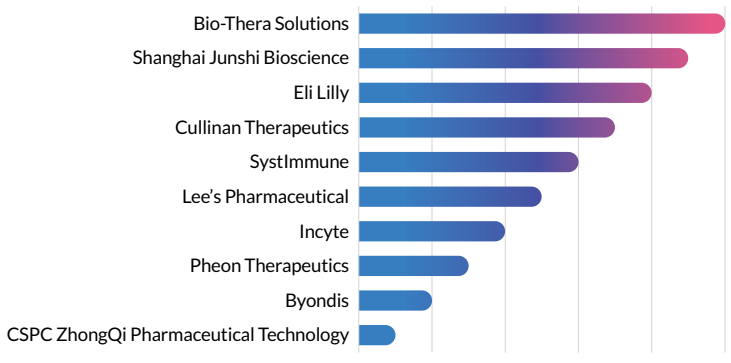
Tivdak is an antibody-drug conjugate (ADC) targeting tissue factor and tubulin. Keytruda is a monoclonal antibody (mAb) that targets the Programmed Cell Death Protein 1 (PD-1)/Programmed Cell Death Ligand 1 (PDL-1) pathway.

DETAILS IN THE DATA: HERE'S WHAT WE LEARNED ABOUT DRUG DEVELOPMENT FOR CERVICAL CANCER

In analyzing our data[8], we identified:

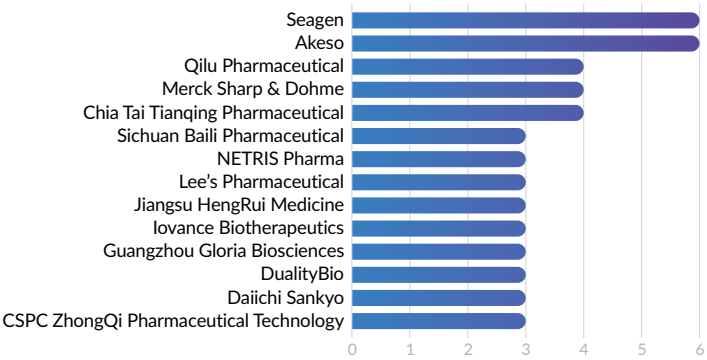
- 117 **ongoing** industry-led, FDA-track interventional clinical development programs* among which:
  - *18 are in Phase 1 or 1b,*
  - *80 are in Phase 2 or 1/2 and*
  - *19 are in Phase 2/3 or Phase 3.*
- The programs mentioned above are conducted by 70 different primary sponsors and correspond to 109 investigational drugs/drug combinations, covering 42 different drug modalities/modality combinations.

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



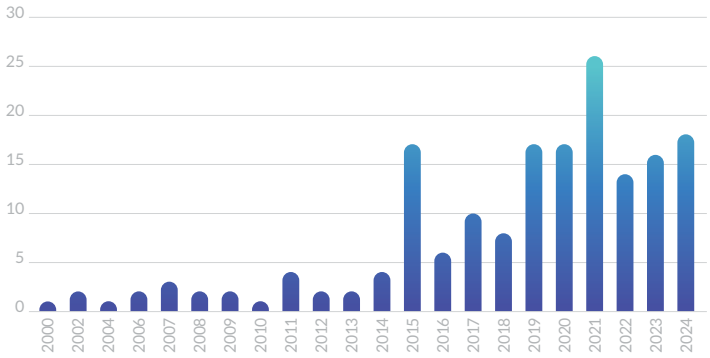
Our pipeline performance score leverages our patented AI-driven probability of technical and regulatory success (PTRS) assessments.

Sponsors With the Highest Number of Active Cervical Cancer Clinical Programs



These are the top sponsors based on the number of ongoing cervical cancer clinical programs.*

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



Over the past two decades, cervical cancer witnessed relatively slow development until 2014-2015, when the advent of immunotherapies seems to have provided a boost. Since then, there has been an upward trend, with 2015 and 2021 being outlier years.

- Among industry-led, FDA-track historical programs, 37% transitioned from Phase 1 to Phase 2 and 26% from Phase 2 to Phase 3.
- There have been thirteen drugs — all from different sponsors — that have not received prior FDA approval in cervical cancer and are being tested in Phase 3 trials.
- The drugs referenced above are mostly mAbs, bispecific antibodies and ADCs.
- Regarding Mechanism of Action (MoA), the most common targets would be the PD-1/PDL-1 pathway and Cytotoxic T-lymphocyte protein 4 (CTLA-4).

PERSPECTIVE: WHAT DOES THIS ALL MEAN?

Cervical cancer is a disease that primarily impacts low-income countries due to limited access to HPV vaccinations as well as the lack of systematic screening. Because the causality of this disease is so well-characterized, major industry focus has been given to preventing the disease through vaccinations and early diagnosis. In fact, in 2020, the World Health Organization (WHO) launched an initiative to eliminate cervical cancer as a public health problem, with 194 countries pledging to reach and maintain an incidence rate of below 4 per 100,000 women. This means that less focus was given in the past on the actual treatment of the disease. Since 2000, less than five separate drugs have received regulatory approval for the treatment of cervical cancer. However, this trend has been reversed, as there are thirteen different sponsors, each testing a separate drug, that have reached the Phase 3 stage of clinical development. This signifies the industry's renewed interest in treating cervical cancer.

Most of these Phase 3 drugs focus on a target that has received regulatory approval in the past, in this specific indication (PD-1/PDL-1 pathway). Seeing as early detection and prevention are already receiving the lion's share of the industry's focus, it appears that for the foreseeable future, the majority of treatment focus will be pointed in the direction of already established targets and pathways.

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 https://www.cancer.gov/types/cervical/treatment#section/all
2 https://www.who.int/activities/immunizing-against-hpv
3 Dunne EF, Park IU. HPV and HPV-associated diseases. Infect Dis Clin North Am. 2013 Dec;27(4):765-78. doi: 10.1016/j.idc.2013.09.001. PMID: 24275269.
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5 Tran NP, Hung CF, Roden R, Wu TC. Control of HPV infection and related cancer through vaccination. Recent Results Cancer Res. 2014;193:149-71. doi: 10.1007/978-3-642-38965-8_9. PMID: 24008298.
6 World Cancer Report 2014. World Health Organization. 2014. pp. Chapter 5.12. ISBN 978-92-832-0429-9.
7 https://www.cancer.gov/types/cervical/treatment
8 Data as of January 7, 2025

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**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.*