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NEW STRONG ORVIGLANCE DATA SUPPORT SUCCESSFUL SPARKLE COMPLETION WITH SUBSTANTIALLY FEWER PATIENTS

SPARKLE EXPECTED COMPLETED BY FEB-MAR 2023
TOPLINE RESULTS BY MID 2023

INVESTOR CALL & PRESENTATION
6 Dec 2022

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ASCELIA PHARMA – COMPANY HIGHLIGHTS

ADVANCING ORPHAN ONCOLOGY

- Identify, develop and commercialize novel drugs that address unmet needs in rare cancers
- Two drugs in advanced clinical development
  - **ORVIGLANCE** – in global Phase 3; FDA Orphan Drug Designation
  - **ONCORAL** – ready for Phase 2

BUILDING GLOBAL CAPABILITIES

- Based in Malmö (Sweden), US affiliate in New Jersey (US)
- Solid balance sheet and financed into Q4 2023
- Listed on NASDAQ Stockholm (Ticker: ACE)

NEW STRONG ORVIGLANCE DATA SUPPORT SUCCESSFUL SPARKLE COMPLETION WITH SUBSTANTIALLY FEWER PATIENTS

- Ascelia Pharma has thoroughly analyzed the new data and original assumptions with statisticians and regulatory experts to validate this important finding

- Based on discussions with the FDA, Ascelia Pharma has decided to change the patient enrolment target of SPARKLE to 80 patients

MILESTONES AHEAD

- Patient enrolment completion by Feb-Mar 2023
- Topline results by mid 2023

PRIMARY ENDPOINT CAN BE REACHED WITH LESS PATIENTS

CONSERVATIVE SPARKLE DESIGN

The original SPARKLE sample size estimate was based on

- Phase 1 and 2 data and literature
- Pre-covid feasibility analysis

Conservative assumptions based on Phase 2 data were applied to account for differences in

- Doses used
- Primary liver cancer vs. metastases
- Technical performance of MRI equipment
- Inter-reader variability

NEW DATA SUPPORT COMPLETION WITH FEWER PATIENTS

New data with the same image reading methodology as in the SPARKLE study demonstrate that

- Two to three times higher effect than the assumed effect in SPARKLE
- Re-read study successful ($p<0.009$) based on 20 patients for lesion visualization (primary endpoint in SPARKLE)
- Other assumptions have also been updated based on now available internal or external data

Statistically significant results can be obtained with substantially fewer patients and strong likelihood of success, while maintaining conservative assumptions

We have thoroughly analyzed the new data available, consulted statisticians and regulatory experts, and discussed with the FDA

DECISION

Based on these discussions, Ascelia Pharma has decided to stop enrollment at 80 patients which is expected to be reached by February/March 2023

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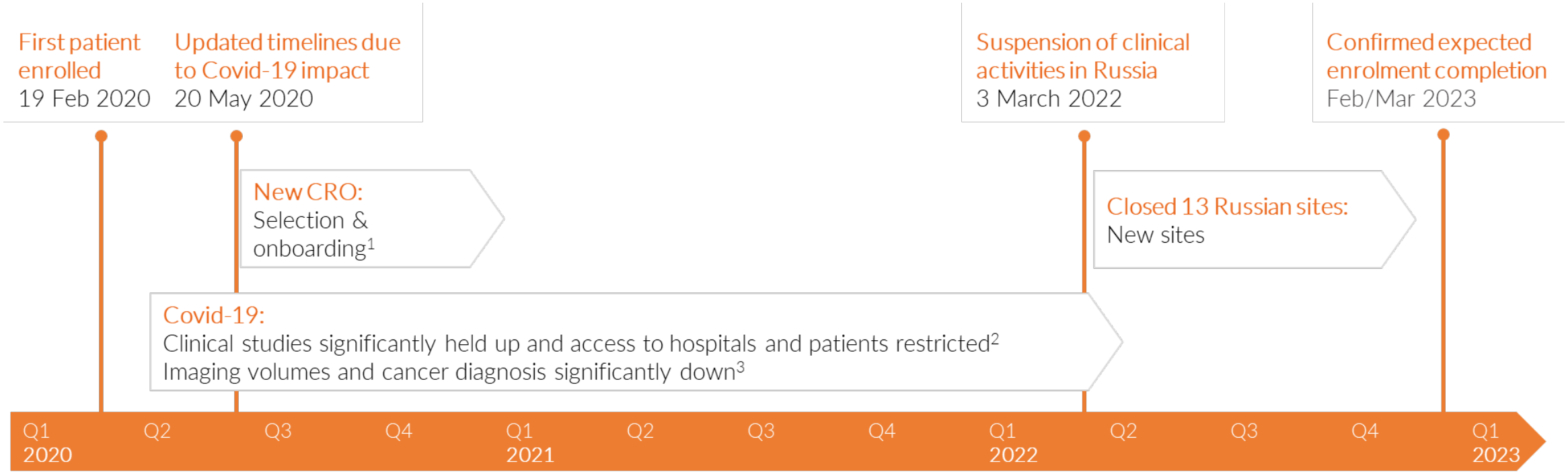
SPARKLE PATIENT RECRUITMENT RAMPED UP IN 2022



Sources:
1) Ascelia Pharma announcement 20 May 2020. Previous CRO experienced liquidity problems and eventually went into bankruptcy .
2) Endpoints News, September 2022: Even as pandemic recedes, short-staffed trial sites leave cancer patients waiting
3) Acad Radiol. 2020 Sep; 27(9): 1204–1213. Radiology Imaging Volume Changes During Discrete COVID-19 Pandemic Waves: Implications for the Delta Variant of Coronavirus and Future Pandemics. J Am Coll Radiol. 2022 Mar; 19(3): 415–422.

PLAN FOR SPARKLE PATIENT ENROLMENT COMPLETION

Status (as per 5 Dec 2022)

- Active sites: 48
- Recruiting sites: 22 (46%)
- Completed patients: 58
- First patient from social media campaign consented

Plan ahead

- Identified pool of potential SPARKLE patients is larger than ever
- Communication of patient enrolment status after the last Friday of every month

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EIGHT COMPLETED CLINICAL STUDIES

- Data presented at major radiology conferences

Phase 1 & 2	Completed (6 studies)	**BLINDED READ STUDY** Safety and efficacy vs. unenhanced in all phase 1 and 2 images (6 studies, including 178 persons and compassionate use)	**Consistent positive results, incl. 33% more lesions** **Delineation** (border sharpness) and **conspicuity** (contrast vs. background): p-value <0.0001
		ORVIGLANCE VS. GADOLINIUM CONTRAST AGENT Orviglance vs. gadolinium (Multihance) and vs. unenhanced (20 persons crossover with 3 independent readers)	**Number of lesions** (3 of 3 higher) **Smaller lesion** detection (3 of 3 higher) **Delineation and conspicuity** (2 of 3 higher)
Phase 3 Program	Completed (1 study)	**FOOD EFFECT STUDY** Evaluates the effect of food intake on absorption and signal intensity (23 healthy volunteers)	**Strong liver enhancement both in fasting condition and with light meal**, support intake of light meal
	Completed (1 study)	**HEPATIC IMPAIRMENT STUDY** Evaluates the effect of liver impairment on the safety, pharmacokinetics and pharmacodynamics	**Well tolerated in patients with liver impairment** Confirms excretion primarily via the liver and not the kidney
	Ongoing (1 study)	**SPARKLE PHASE 3 PIVOTAL STUDY** Evaluates the safety and efficacy in target patient population (enrollment not yet completed	Pivotal study patient enrollment planned completed in Feb/Mar 2023

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DEVELOPMENT PROGRESS ON TRACK

Safety	Data Safety Monitoring Board (DSMB) review conducted (n=30) • Nausea reported as the most frequent related AE (n=5) • No serious related AEs reported	Trial to proceed without modifications
Pediatric	FDA waiver due to Orphan Drug status EMA approved Pediatric Investigational Plan (PIP; requirement) with dose finding study in 8 patients (post adult approval)	Pediatric indication expected with minimal post-approval additional data required
Supply Chain	First commercial size drug product batch completed Supply chain designed from drug substance to end customer	On track for NDA and launch timelines

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PRIORITIES AHEAD

- Patient enrollment completion by Feb/Mar 2023

- Topline results by mid 2023

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