

CORPORATE OVERVIEW

July 2024



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Actuate Therapeutics, Inc. (the "Company," "Actuate," "we," "our" and "us") has filed a registration statement (including a preliminary prospectus) on Form S-1 (File No. 333-279734) related to this proposed initial public offering with the Securities and Exchange Commission (the "SEC"). The registration statement has not yet become effective. Shares of our common stock may not be sold, nor may offers to buy be accepted, prior to the registration statement becoming effective. Before you invest, you should read the preliminary prospectus in that registration statement, and when available, the final prospectus relating to the offering, and the other documents we have filed with the SEC for more complete information about us and the proposed offering. You may get these documents for free by visiting EDGAR on the SEC website at ww.sec.gov. Alternatively, a copy of the prospectus may be obtained from Titan Partners Group LLC, a division of American Capital Partners, LLC at 4 World Trade Center, 29th Floor, New York, NY 10007, by phone at (929) 833-1246 or by email at prospectus@titanpartnersgrp.com.

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Company Highlights

- 1
- Developing elraglusib, a leading GSK-3β inhibitor with novel, multimodal MOA, in multiple advanced cancer Phase 2 trials

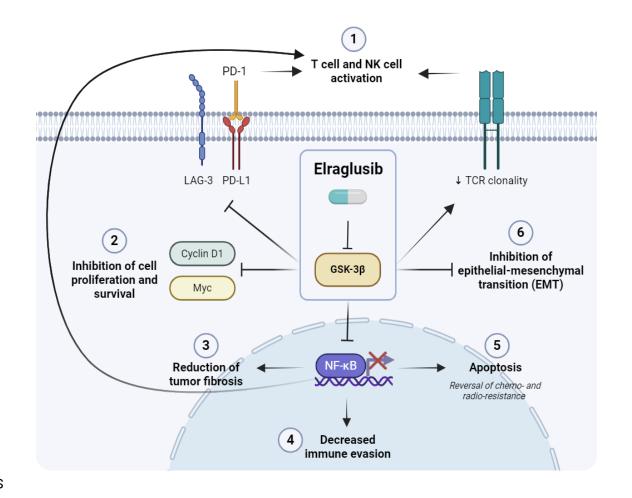
- 2
- Clinical responses (CRs/PRs) and Disease Control observed across cancer histologies with elraglusib IV as single agent and in combination with chemotherapy
- 3
- Extended survival and increased responses are observed in mPDAC and relapsed/ refractory Ewing sarcoma. Preliminary evidence of clinical benefit has also been observed in patients with metastatic melanoma and relapsed/refractory colorectal and lung cancer, which will be used to inform prioritization of the near-term pipeline
- 4
- Oral version of elraglusib successfully evaluated in Healthy Volunteer Phase 1
 - Potentially expands clinical and commercial opportunities

- 5
- Broad composition of matter IP protection and development incentives
 - Orphan Drug and Fast Track Designations for pancreatic or other cancer types could accelerate path to registration



Multimodal MOA Supported by Clinical Data

- Elraglusib is an ATP-competitive inhibitor of GSK-3β
 - GSK-3β has been shown to potentially contribute to tumor progression in many treatment naive and refractory/resistant tumors
 - Pleiotropic effects as signaling adaptor
- Elraglusib downregulates well-credentialed molecular pathways that can lead to chemotherapy and drug resistance
 - NF-kB pathway-anti-apoptotic protein expression
 - Alterations in TGF-b and pro-inflammatory cytokines suggest role in fibrosis in addition to immunomodulation
 - DDR pathways (ATR/ATM) including mismatch repair (PMS2)
 - Increase responsiveness of resistant/refractory tumors to chemo and immune therapy-"cold" tumors turned to "hot"
 - Inhibition of oncogenic epithelial-mesenchymal transitions

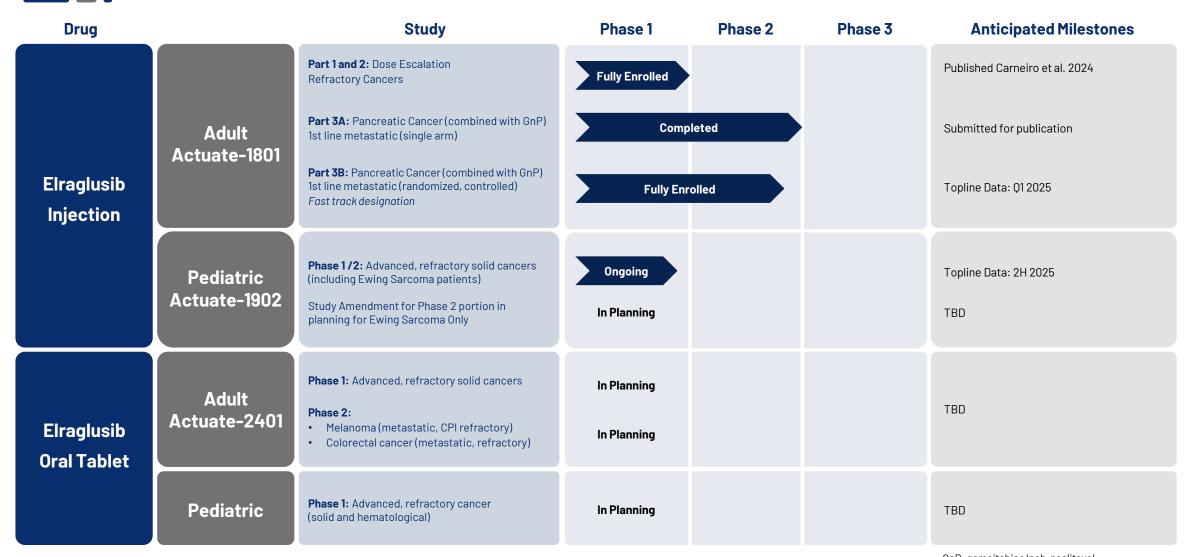




Multimodal MOA Supported by Clinical Data

Within each study (1801, 1902, 2401), each subsequent part or phase is successive to the preceding part or phase

and not a separate study that will individually proceed through each of phases 1, 2, and 3 of clinical trials.



Note: As of May 2024

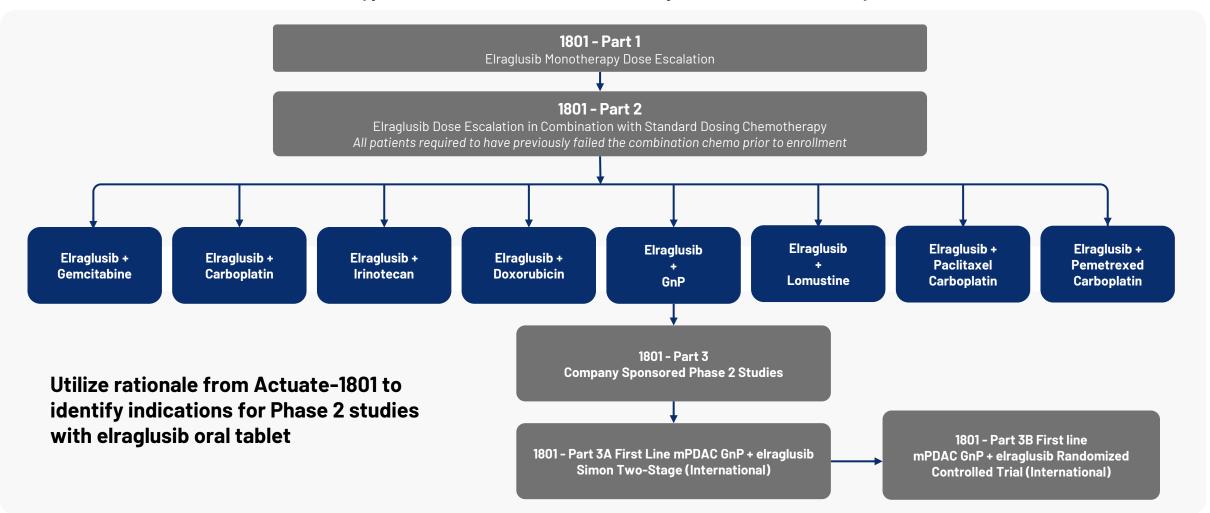
GnP: gemcitabine/nab-paclitaxel FPFD: First patient first dose RP2D: Recommended Phase 2 Dose



Clinical Study Actuate-1801

Phase 1/2 Study Design for Elraglusib Injection

Establishes process for transition from elraglusib (9-ING-41) Monotherapy (Part 1) to evaluation of multiple chemotherapy combinations (Part 2) to Phase 2 efficacy studies (Part 3) under one protocol





Safety Profile of Elraglusib

As Monotherapy and in combination with chemotherapy

Treatment-Emergent Adverse Events of Any Grade Reported in ≥20% of Patients Treated with elraglusib in Actuate 1801 Part 1 and 2

Treatment-Emergent Adverse Events of Any Grade Reported in ≥20% of Patients Treated with elraglusib (December 31, 2023) in Actuate 1801 Part 3B (ongoing)

| Patients, n (%) | | | | | Patients, n (%) | | | | |
|--|--|--------------|--|--|---------------------------------------|---|------------|-------------------------------------|-----------|
| Adverse event | Elraglusib monotherapy Part 1(N=67) | | Elraglusib with chemotherapy Part 2 (N=171) | | Adverse event | Elraglusib with Nab-Paclitaxel + Gemcitabine (N=139) | | Nab-Paclitaxel + Gemcitabine (N=62) | |
| | Any Grade | Grade ≥3 | Any Grade | Grade ≥3 | | Any Grade | Grade ≥3 | Any Grade | Grade ≥3 |
| Any TEAE | 67(100) | 37(55.2) | 171 (100) | 124 (72.5) | Any TEAE | 128 (92.1) | 105 (75.5) | 54 (87.1) | 33 (53.2) |
| Serious TEAE | 29 (43.3) | 26 (38.8) | 72 (42.1) | 67(39.2) | Serious TEAE | 63 (45.3) | 60 (43.2) | 25 (40.3) | 23 (37.1) |
| Leading to treatment discontinuation | 6(9) | 4(6) | 36 (21.1) | 30 (17.5) | Leading to Stoppage of Any Study Drug | 19 (13.7) | 16 (11.5) | 8 (12.9) | 8 (12.9) |
| Leading to death | 5 (7.5) | 5 (7.5) | 18 (10.5) | 18 (10.5) | Leading to death | 13 (9.4) | 13 (9.4) | 8 (12.9) | 8 (12.9) |
| TEAEs of any Grade in ≥20% of Patients | | | | TEAEs of any Grade in ≥20% of Patients | | | | | |
| Visual impairment | 34 (50.7) | 0 | 104 (60.8) | 1(0.6) | Visual impairment | 80 (57.6) | 0 | 3 (4.8) | 0 |
| Fatigue | 32 (47.8) | 2(3) | 86 (50.3) | 8 (4.7) | Neutropenia ¹ | 67(48.2) | 63 (45.3) | 17 (27.4) | 11 (17.7) |
| Nausea | 25 (37.3) | 1(1.5) | 77 (45) | 3 (1.8) | Fatigue | 64 (46) | 15 (10.8) | 18 (29) | 1(1.6) |
| Diarrhea | 21(31.3) | 3 (4.5) | 52 (30.4) | 6 (3.5) | Nausea | 61(43.9) | 10 (7.2) | 19 (30.6) | 1(1.6) |
| Anemia | 17 (25.4) | 4(6) | 80 (46.8) | 43 (25.2) | Diarrhea | 57 (41) | 11(7.9) | 19 (30.6) | 2(3.2) |
| Vomiting | 17 (25.4) | 1(1.5) | 47(27.5) | 5 (2.9) | Anemia ² | 45 (32.4) | 25 (18) | 14 (22.6) | 8 (12.9) |
| Headache | 16 (23.9) | 0 | 36 (21.1) | 1(0.6) | Alopecia | 43 (30.9) | 1(0.7) | 18 (29) | 0 |
| Abdominal pain | 12 (17.9) | 3 (4.5) | 38 (22.2) | 6 (3.5) | Decreased appetite | 41(29.5) | 5 (3.6) | 9 (14.5) | 2(3.2) |
| Neutrophil count decrease | 2(3) | 2(3) | 45 (26.3) | 36 (21.1) | Thrombocytopenia ³ | 38 (27.3) | 11(7.9) | 12 (19.4) | 2(3.2) |
| Platelet count decrease | 1(1.5) | 0 | 50 (29.2) | 27 (15.8) | Vomiting | 36 (25.9) | 2 (1.4) | 15 (24.2) | 1(1.6) |
| White blood cell count decrease | Not reported | Not reported | 42 (24.6) | 28 (16.3) | Constipation | 36 (25.9) | 2 (1.4) | 14 (22.6) | 1(1.6) |

Key Takeaways

Most adverse events when used as monotherapy were reported as mild to moderate

- Transient visual impairment described as transient alterations in color and skin tones under fluorescent light
- No permanent changes to eye structure or vision
- Visual impairment and fatigue are the two most frequent adverse events attributed to elraglusib
- Visual impairment decreases after a few cycles of treatment

- l. Includes PT terms neutropenia and neutrophil count decreased
- 2. Includes PT terms anemia and hemoglobin decreased
- 3. Includes PT terms thrombocytopenia and platelet count decreased



1st Line Treatment of mPDAC

Phase 2 - Actuate 1801 Part 3A

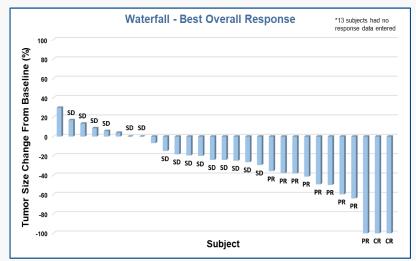
- Simon's two-stage design Stage 1
- 1st line metastatic pancreatic cancer (mPDAC)
- Evaluate combination of elraglusib and gemcitabine/nab-paclitaxel(GnP)
- First 23 consecutively evaluable patients defined as analysis set n= 29 after replacing non-evaluable patients (EE population)
 - 2 CRs confirmed
 - 9 PRs confirmed
 - DCR: 52%, ORR: 38%
 - Met Simon's stage 1 threshold of DCR>50%
- 42 total patients enrolled (ITT)

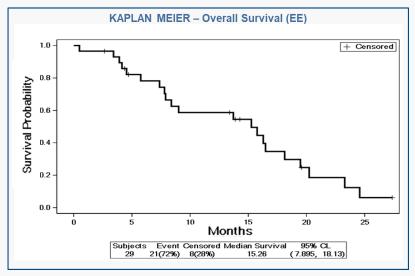
Evaluation of best overall response and CA19-9 in ITT

Evidence for clinical activity based on tumor and CA19-9 response

Based on these data, we pivoted to a Phase 2 RCT

- N=286
- Randomized (2:1), controlled
- Elraglusib + GnP vs GnP alone







Phase 2 RCT

Primary endpoint: OS

Secondary endpoints: ORR, DOR, PFS

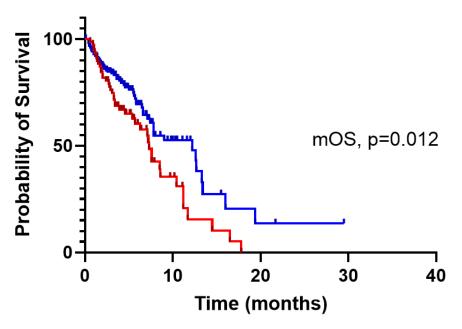
Total enrollment: 286 (completed Jan 2024)

• Sample size based on increase in 1 year OS from 35% in GnP to 55% in elraglusib/GnP with α =0.05; 232 patients needed for 80% power

| | GnP (78) | Elraglusib/GnP (155) | |
|-------------------|-------------|-------------------------|---------------------------|
| os | | | |
| mOS (months) | 7.3 | 12.2 | HR=0.60; log-rank p=0.012 |
| Events (% events) | 42 (53.8%) | 53 (34.2%) | |
| 12-month 0S(%) | 15.5 | 52.5 | |
| 18-month OS(%) | 0 | 20.5 | |
| 24-month 0S(%) | 0 | 13.6 | |
| PFS | | | |
| mPFS (months) | 4.6 | 4.8 | HR=0.90; P=NS |
| Events (% events) | 50 (64.1%) | 79 (51%) | |
| ORR | | | |
| n(%) | 12 (24%) | 32 (30.8%) | Evaluable for response |

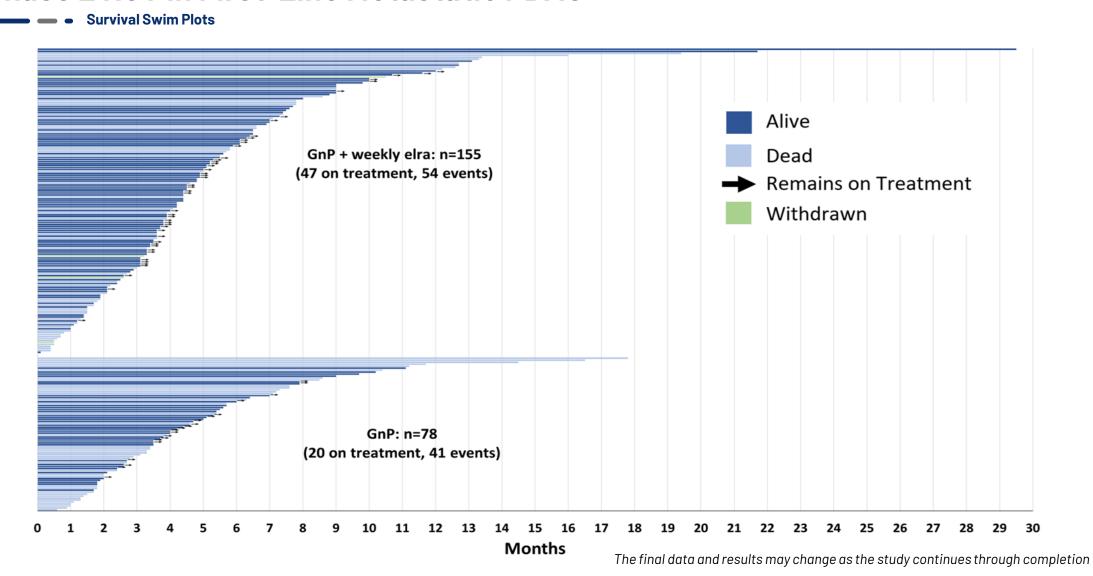
Analysis of the interim data from Actuate-1801 3B is based on the study statistical analysis plan for informal interim data analysis when >50% of the patients in the GnP control group progressed and were no longer receiving GnP.

GnP + weekly elra (n=155, 47 on treatment, 53 events)



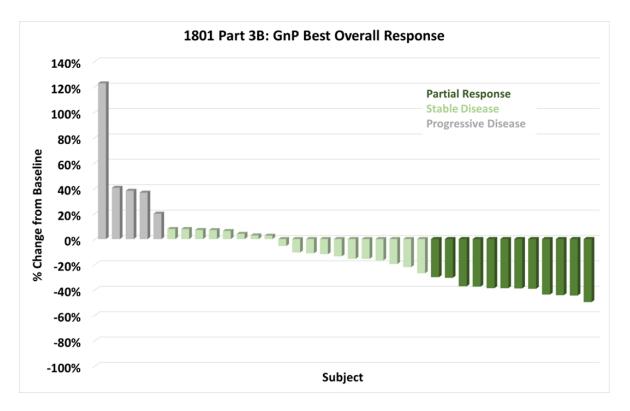
The final data and results may change as the study continues through completion

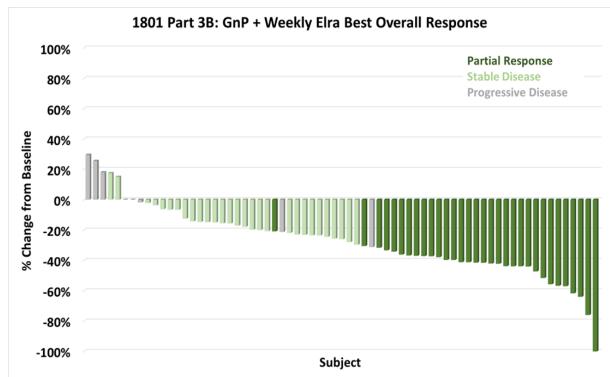






Best Overall Response Waterfall Plots

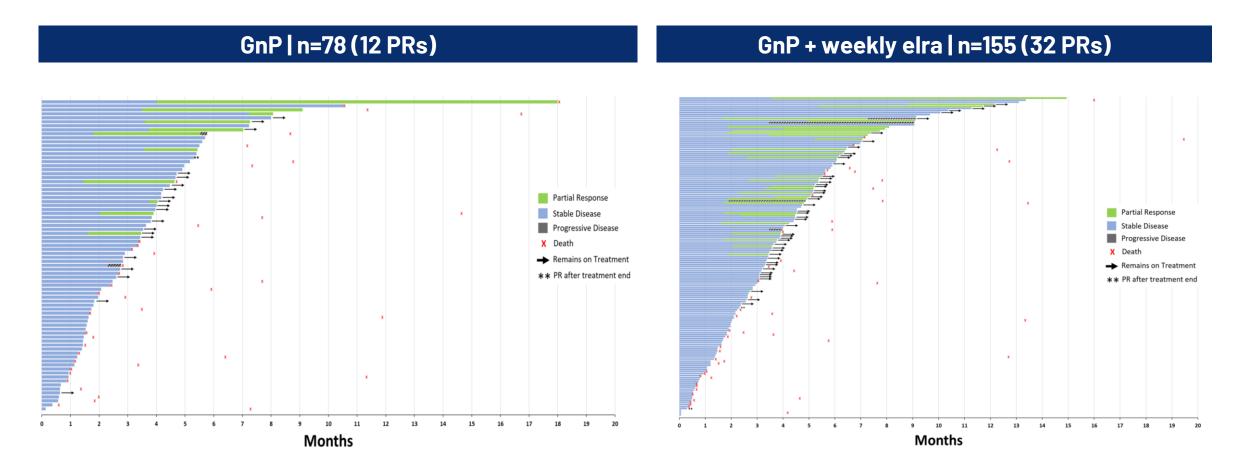




The final data and results may change as the study continues through completion



Time on Treatment Swim Plots



The final data and results may change as the study continues through completion



Patient Demographics

a as of May 1, 2024

| | Demographics – 1801 3B | GnP (N = 78) | GnP + Weekly Elra (N=155) |
|--------|--------------------------------------|--------------|---------------------------|
| Sex | | | |
| | Female | 35 (44.9%) | 75 (48.4%) |
| | Male | 43 (55.1%) | 80 (51.6%) |
| Age (y | /ears) | | |
| | n(%) | 78 (100%) | 155 (100%) |
| | Mean (S.D.) | 66.0 (9.9) | 65.1(9.1) |
| | Median | 67.0 | 65.0 |
| | Min, Max | 42.0, 85.0 | 42.0, 86.0 |
| Race | | | |
| | Asian | 2(2.6%) | 5 (3.2%) |
| | Black or African American | 6 (7.7%) | 7(4.5%) |
| | White | 65 (83.3%) | 128 (82.6%) |
| | Multiracial | 0 | 1(0.6%) |
| | Unknown/Not Reported | 5(6.4%) | 14 (9.0%) |
| Ethnic | eity | | |
| | Hispanic or Latino | 0 | 8 (5.2%) |
| | Not Hispanic or Latino | 77 (98.7%) | 141 (91.0%) |
| | Unknown/Not Reported | 1(1.3%) | 6 (3.9%) |
| Height | t (inches) | | |
| | n(%) | 77(98.7%) | 155 (100%) |
| | Mean (S.D.) | 67(4) | 66 (4) |
| | Median | 67 | 67 |
| | Min, Max | 59, 76 | 42, 76 |
| Weigh | it (pounds) | | |
| | n (%) | 78 (100%) | 155 (100%) |
| | Mean (S.D.) | 159.0 (42.2) | 159.8 (38.3) |
| | Median | 154.4 | 156.3 |
| | Min, Max | 85.3, 343.3 | 84.5, 335.0 |
| Body S | Surface Area (BSA) (m2) | | |
| | n(%) | 78 (100%) | 154 (99.4%) |
| | Mean (S.D.) | 1.83 (0.26) | 1.82 (0.22) |
| | Median | 1.82 | 1.81 |
| | Min, Max | 1.31, 2.77 | 1.30, 2.41 |
| Easte | rn Cooperative Oncology Group Perfor | mance Status | |
| | 0 | 31(39.7%) | 64 (41.3%) |
| | 1 | 44 (56.4%) | 88 (56.8%) |
| | 2 | 2(2.6%) | 2(1.3%) |

| General Classification of Pancreatic Cancer (at initial diagnosis) | GnP (N = 78) | GnP + Weekly Elra (N=155) |
|--|--------------|---------------------------|
| Borderline resectable pancreatic carcinoma | 0 | 9(5.8%) |
| Locally advanced pancreatic carcinoma | 5(6.4%) | 10 (6.5%) |
| Metastatic pancreatic carcinoma | 64(82.1%) | 116 (74.8%) |
| Resectable pancreatic carcinoma | 8 (10.3%) | 20 (12.9%) |
| Pancreatic carcinoma NOS | 1(1.3%) | 0 |

Site of Metastases

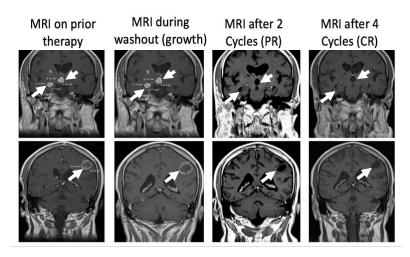
| Anatomical Location | GnP (N = 78) | GnP + Weekly Elra (N=155) |
|---------------------|--------------|---------------------------|
| Pancreas | 73 (93.6%) | 127(81.9%) |
| Liver | 67(85.9%) | 115 (74.2%) |
| Lymph Node (BSA) | 29 (37.2%) | 71(45.8%) |
| Lung | 27(34.6%) | 57(36.8%) |



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Clinical Activity in Areas of High Unmet Need in 1801 Part 1 and 2

- Actuate 1801 Part 1 evaluated elraglusib as a single agent
 - Extraordinary results for two melanoma patients in the study
 - First objective response reported in patient treated with 5 mg/kg elraglusib monotherapy
 - Metastatic melanoma diagnosed in 2018; widely metastasized to the brain, lungs, bones, muscles, stomach, lymph nodes, pancreas and adrenal glands.
 - Refractory to all FDA-approved standard therapies, including several checkpoint inhibitors and BRAF / MEK inhibitor
 - After 12 Weeks on elraglusib: Brain MRI showed complete response (CR) by RANO criteria, PET scan showed complete metabolic response ("CMR").
 - Durable CMR ongoing (>5.0 years as of February 1, 2024)
- Refractory, metastatic melanoma identified as clinical indication for elraglusib development
 - A second patient receiving single agent elraglusib has ongoing stable disease (SD)(3.1 years as of last documented alive date)
 - Also failed all FDA-approved standard therapies including immune checkpoint inhibitors and several experimental treatments
 - Patients receiving chemotherapy salvage after anti-PD-1 treatment have a mOS of 6.9 months across all chemotherapy tested¹
 - Potential for biomarker enrichment to improve probability of success



12 weeks on elraglusib leads to Complete Response by PET-MRI. Cystic lesions observed in place of prior tumor

| Combination | Key Histologies | mOS (1801) | | |
|---|---|--|--|--|
| Elraglusib/Gemcitabine/ nab-paclitaxel | Metastatic Pancreatic Cancer (mPDAC) | 15.3 months (Part 3A) 12.2 months (Part 3B) | | |
| Elraglusib Monotherapy | Refractory, Metastatic Melanoma | 9.1 months | | |
| Elraglusib/Irinotecan | Refractory, metastatic Colorectal | 6.9 months | | |

Goldinger at el., Eur J Cancer 2022; 162: 22.



Clinical Responses in Areas of High Unmet Need-Pediatric Oncology

Objective responses and durable survival highlight development opportunity in Ewing sarcoma



Phase 1/2 study (Actuate-1902) in pediatric cancer patients with recurrent/refractory solid cancers



There are currently no treatment regimens that meaningfully extend life in Ewing sarcoma patients with metastatic, refractory disease



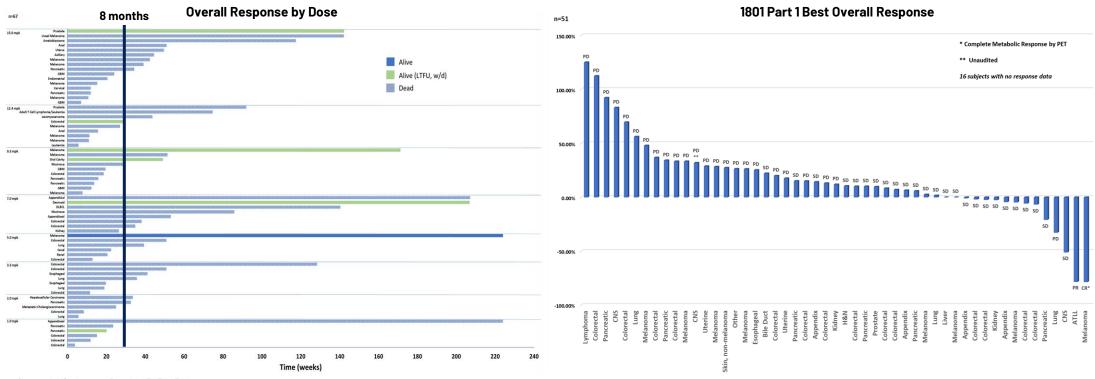
Patients that have metastasis and disease recurrence after chemotherapy have short survival of 3-8 months¹

- Seven patients were enrolled in Actuate-1902 and appear to have metastatic, refractory Ewing and Ewing-like sarcoma and had disease progression on their last treatment regimen prior to joining the study
- All seven patients received the combination of elraglusib+cyclophosphamide/topotecan in 1902
- Four out of seven patients had received two or more previous chemotherapy regimens
- One patient had CR at their 1st scan as Best Overall Response (BOR)
 - Stopped all treatments after four months and continues to be in complete remission with no evidence of disease almost two years after termination of treatment
- One patient had BOR of CMR (Complete Metabolic Response, no detectable lesions by FDG-PET);
- One patient had BOR of PR (52% reduction in tumor)
- Two patients had BOR of SD and one patient had BOR of PD
- Four patients remain alive and three continue on treatment



Higher Doses of Elraglusib Appear Associated with Better Overall Survival

- Single agent dose escalation (Actuate-1801 Part 1) was evaluated in 67 patients in 15 different cancer types¹
- 35/67 subjects were enrolled at the three highest doses (9.4, 12.4 and 15 mg/kg)
- Patients were advanced, refractory patients that had been heavily pre-treated [median 3 (1-13)]
- A large number of patients had prolonged overall survival (OS) and some tumor shrinkage even of it did not reach level of an objective response at these higher doses of elraglusib single agent
- Similar dose-response observed with chemotherapy combinations in Actuate-1801 Part 2
- mOS 7.7 month in Actuate-1801 Part 1 benchmarks favorably with published data for clinically active agents in Phase 1 (mOS~8-10 months^{2,3})



- Carneiro et al Clin Cancer Res 2023: 30: 522
- Menon et al., 2022 Cancer Rep (Hoboken); 5: e1465
- 3. Paluri et al. Scientific Rep



Elraglusib Clinical Pharmacology

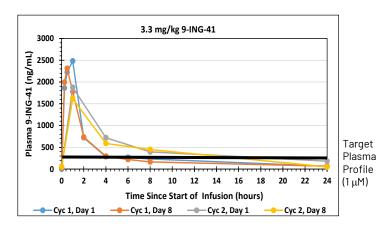
Supports Additional Dose Exploration

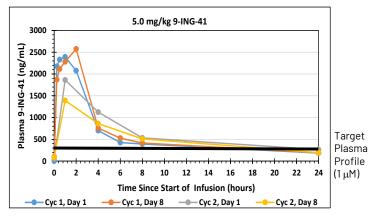
Plasma Pharmacokinetics (PK) after a Single IV Dose in Actuate-1801 Part 1

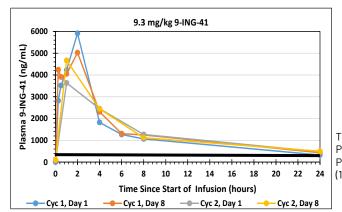
| | | | | - | | | | | | |
|---------------|-----|---------------|-----------|------------------|------------------|-----------------|-----------|-----------|--------------|------------|
| Dose mg/kg | n | Cmax ng/mL | Tmax H | AUC24 ng•h/mL | AUC72 ng•h/mL | AUC∞ ng•h/mL | λz 1/h | t1/2 h | CL L/h/kg | Vz L/kg |
| 1 | 2-3 | 560.5 | 1.067 | 2,961 | 6,145 | 4,648 | 0.1027 | 16.76 | 0.2854 | 4.427 |
| 2 | 5-5 | 1242 | 1.110 | 5 932 | 9 271 | 8 002 | 0.05622 | 15.63 | 0.2915 | 5.529 |
| 3.3 | 4-5 | 1,930 | 1.577 | 11,571 | 15,150 | 13,097 | 0.08754 | 11.33 | 0.2775 | 4.262 |
| 5 | 5-5 | 1896 | 2.200 | 15 191 | 23 771 | 29 335 | 0.03094 | 31.93 | 0.2067 | 7.605 |
| 7 | 5-7 | 4,027 | 1.388 | 30,151 | 48,433 | 47,971 | 0.04612 | 24.75 | 0.1835 | 5.555 |
| 9.3 | 7-8 | 4 146 | 1.036 | 31 160 | 50 405 | 63 358 | 0.03827 | 28.79 | 0.1953 | 6.446 |
| 12.37 | 5-5 | 6 912 | 2.080 | 44 094 | 84 381 | 86 579 | 0.04856 | 15.24 | 0.1881 | 4.090 |
| 15 | 1-2 | 4,300 | 1.067 | 62,376 | 84,367 | 87,580 | 0.02908 | 36.18 | 0.1713 | 3.717 |
| | | | | | | | | | | |

- Range of clinical benefit for elraglusib injection is hypothesized at 5 mg/kg and above based on PK data in patients¹
- Exceeds in vitro IC50 for tumor cell line death/apoptosis in preclinical studies for >12 hours
- These doses lead to plasma exposure of elraglusib of up to 87,850 ng•h/mL

Mean Plasma 9-ING-41 (elraglusib) Concentration-Time Profiles in Actuate-1801 Part 1







Target Plasma Profile (1 µM)

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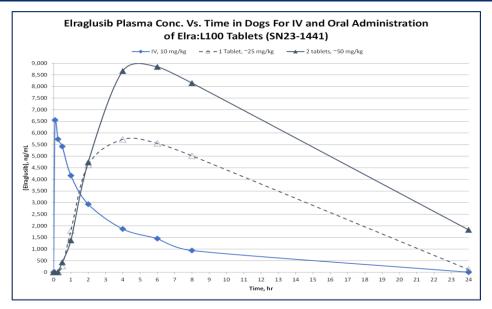
Carneiro et al Clin Cancer Res 2023: 30: 522

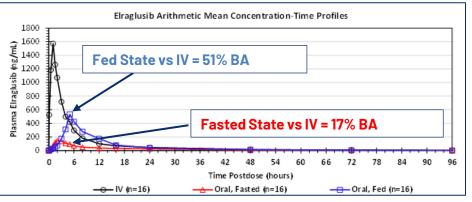


Elraglusib Oral Formulations

Oral elraglusib formulations have been developed that provide similar drug exposures to current IV

- Several possible oral dosage forms may allow potential expansion into pediatric cancer indications and adult indications where standard of care is oral
- May improve compliance and patient experience in indications where long DCR is observed
- Decreased cost of manufacturing at commercial scale compared to IV formulations
- Phase 1 Study of Oral Solution in Normal Healthy Volunteers (NHV) recently completed
 - Oral Solution vs IV >50% bioavailability when dosed with food
 - Exposure and pharmacodynamic effects exhibited in fed/fasted patients
- Phase 1 dose escalation study using Elraglusib Oral Tablet in advanced cancer patients (not healthy volunteers) in planning







Elraglusib Oral Tablet

Exceeds Plasma Exposures of Elraglusib Injection

Elraglusib Oral Tablet Plasma Exposure (AUC) at MTD is similar to the Highest Dose of elraglusib Injection tested to date

| Route | Potency | Dose Number | Target Dose (mg/kg) | Actual Dose (mg/kg) | Half-life (hr) | T _{max} (hr) | C _{max} (ng/mL) | AUC _{last} (hr*ng/mL) | Dose-limiting Toxicity |
|-------|---------|-------------|------------------------|------------------------|-------------------|--------------------------|-----------------------------|-----------------------------------|---------------------------|
| IV | N/A | 1 | 10 | 10 | 2.63 | 0.0830 | 6,560 | 22,300 | No |
| Oral | 250 mg | 2 | 25 | 24.5 | 3.01 | 4.50 | 6,090 | 77,000 | No (MTD) |
| Oral | 500 mg | 3 | 50 | 49.9 | 7.63 | 6.00 | 9,230 | 137,000 | Yes |

- Pharmacokinetics to date have been largely dose-proportional
- Elraglusib Oral Tablet will be given daily, which should achieve steady state plasma levels of drug
- Elraglusib Oral Tablet should achieve daily exposures that are similar to what was previously delivered twice weekly using the IV formulation
 - Flat oral dosing vs IV dosing based on weight simplify use and may improve patient compliance
 - MTD in dogs after a single dose is approximately 25 mg/kg elraglusib Oral Tablet 250 mg
- Population PK studies have demonstrated that elraglusib does not increase plasma levels of any of the chemotherapy backbones evaluated to date (gemcitabine, nabpaclitaxel, irinotecan, cyclophosphamide/topotecan)
- These studies have also demonstrated that the only known toxicity observed to date with elraglusib Injection have correlated with plasma exposure is the visual impairment
- Elraglusib Injection did not accumulate in plasma when given on Days 1 and 4 in Actuate-1801 Part 1 and 2
- This will allow further exploration of risk-benefit, dose and anti-cancer activity in indications identified as promising in Actuate-1801



Key Near Term Anticipated Development Plans and Milestones

IV Program

Part 3A paper EMA advice PFS in >80% FDA Type D Topline data 1801 meeting Phase 2 mPDAC (PDAC) OS in 70% of **mPDAC** control patients PDAC ODD PDAC EMA / COMP 2024 2025 July September December 1H 2025 2H 2025 **August October** November ODD Application Request Type B Meeting to Topline data EMA advice 1902 Phase 1/2 1902 discuss EWS AA/BTD meeting to Fast Track Application discuss **EWS** ODD EWS registration EMA / COMP PiP Request PRIME designation



Actuate Patent Portfolio

United States

US 8,207,216-licensed from UIC

Claims directed to compounds, pharmaceutical compositions, and methods of use Expires March 16, 2028, Eligible for Patent Term Extension (PTE) (March 16, 2033) Pediatric Exclusivity: +6 months

Europe

EP 2125683 (Germany, France, United Kingdom, Italy, Spain)

Claims directed to compounds, pharmaceutical compositions, and uses Expires December 19, 2027

Canada

CA 2673368

Claims directed to compounds, pharmaceutical compositions, and uses Expires December 19, 2027

International

9-ING-41 Polymorph I Composition of Matter: Patent Issued (10/5/2021) US 11,136,334 Patent Application No. PCT/US2018/046203, filed August 10, 2018 Expires August 10, 2038, Potentially Eligible for Patent Term Extension (PTE) Claims directed to Polymorph I, compounds, pharmaceutical compositions, methods of preparing, and uses for treating cancers

Polymorph compositions allowed/issued: US, EPO, Japan, China, Mexico, others

9-ING-41 Polymorph II Composition of Matter: Patent issued (8/9/2022): US 11,407,759 International Patent Application No. PCT/US2018/056083, filed October 16, 2018 Expires October 16, 2038, Potentially Eligible for Patent Term Extension (PTE) Claims directed to Polymorph II, compounds, pharmaceutical compositions, methods of preparing, and uses for treating cancers

Polymorph compositions allowed/issued: US, EPO, Japan, China, Mexico, others

World-Wide: National Stage Applications Pending in North America, Asia, Europe, South America, Israel, Africa and Australia

International Patent Application No. PCT/US2019/032639, filed May 16, 2019

Claims directed to methods and compositions for using, to treat idiopathic pulmonary fibrosis with GSK-3b inhibitors Expires May 16, 2039, Potentially Eligible for Patent Term Extension (PTE)

International Patent Application No. PCT/US2019/035576, filed June 5, 2019

Claims directed to methods and compositions for using, to treat malignant lymphoproliferative disorders Expires June 5, 2039, Potentially Eligible for Patent Term Extension (PTE)

International Patent Application No. PCT/US2020/066762, filed December 23, 2020

Claims directed to methods of treating myelofibrosis using GSK-3b inhibitor, as a single agent or combined with a JAK inhibitor like ruxolitinib.

WW National Stage June 26, 2022 Expires December 23, 2040, Potentially Eligible for PTE

International Patent Application No. PCT/US2023/069518, filed June 27, 2022

Claims directed to oral dosage forms of elraglusib

WW National Stage December 27, 2024 Expires June 27, 2042, Potentially Eligible for PTE

International Patent Application No. PCT/US2019/032639, filed May 16, 2019

Claims directed to methods and compositions for using, to treat idiopathic pulmonary fibrosis with GSK-3b inhibitors Expires May 16, 2039, Potentially Eligible for Patent Term Extension (PTE)

International Patent Application No. PCT/US2019/035576, filed June 5, 2019

Claims directed to methods and compositions for using, to treat malignant lymphoproliferative disorders Expires June 5, 2039, Potentially Eliqible for Patent Term Extension (PTE)

International Patent Application No. PCT/US2020/066762, filed December 23, 2020

Claims directed to methods of treating myelofibrosis using GSK-3b inhibitor, as a single agent or combined with a JAK inhibitor like ruxolitinib.

WW National Stage June 26, 2022 Expires December 23, 2040, Potentially Eligible for PTE



Investment Highlights



Leading Therapeutic Profile

Extensive data on activity from leading research institutions and promising clinical data in multiple cancer histologies



Significant Unmet Needs

Developing elraglusib to address therapeutic shortcomings in key difficult-to-treat and refractory tumors



Complementary Mechanisms of Action

Focus on mediating cancer cell survival and chemoresistance through regulation of NF-kB and regulating antitumor immune response



Robust IP Portfolio

Expansive, global patent portfolio with significant exclusivity runway



Clearly Defined Regulatory Path

Multiple key regulatory designations available (Fast Track, Orphan Drug, Rare Pediatric) with registration path clinical trials underway and in development



Seasoned Leadership Team

Distinguished leadership and recognized world leading scientific advisory team

