



**ZIOPHARM Oncology**

**BETTER CANCER MEDICINE**

**Jonathan Lewis, MD, PhD**  
Chief Executive Officer

[www.ziopharm.com](http://www.ziopharm.com)

## FORWARD-LOOKING STATEMENTS

---

Some of the statements made in this presentation are forward-looking statements. These forward-looking statements are based upon our current expectations and projections about future events and generally relate to our plans, objectives and expectations for the development of and commercialization of in-licensed cancer drugs. Although management believes that the plans and objectives reflected in or suggested by these forward-looking statements are reasonable, all forward-looking statements involve risks and uncertainties and actual future results may be materially different from the plans, objectives and expectations expressed in this presentation.



# ZIOPHARM Oncology, Inc.

---

- Specialty cancer company in-licensing, developing and marketing proprietary products
- Managing risk / benefit by applying new biologic understanding to cancer products
  - In-licensed at preclinical stage or beyond
  - Related molecule efficacy in humans



# Recent Financing News

---

- \$37MM private placement
- New and existing biotechnology investors worldwide:
  - ProQuest Investments
  - ADIA
  - LB I Group, Inc. (Lehman Brothers)
  - Medical Strategy
- Fund development of ZIO-101 and ZIO-201
  - Initiation of pivotal trials expected 2007



# Company Status

---

- Two product families in-licensed
  - Process ongoing
- Two lead candidates in phase I and I/II trials
  - Ongoing and interim data in 2006
  - Pivotal trials planned to initiate 2007
  - Combined sales potential >\$800MM
- Public company (OTC BB: ZIOP)
  - \$37MM financing May 2006
  - ~15.3MM common shares outstanding



# Expected Upcoming Developments

---

- 2006
  - √ Initiate ZIO-101 phase I/II trial in advanced myeloma
  - √ Initiate ZIO-201 phase I/II trial in advanced sarcoma
  - √ ZIO-201 preclinical data at BMT
  - √ ZIO-101 and ZIO-201/analogues preclinical data at AACR
  - ZIO-101/201 ongoing phase I data
  - Initiate additional phase II trials
  - Interim phase I/II and phase II data
  - Additional in-licensing
  - New exchange listing
- 2007
  - ZIO-101/201 phase II data
  - ZIO-101/201 pivotal trial initiation





# ZIO-101 – Organic Arsenic

- First in a new class of molecules
- Issued U.S. patents and applications internationally
- Potentially safer and more active for cancer treatment than approved inorganic arsenic



# ZIO-101: Related Molecule

---

- Inorganic arsenic approved for APL with FDA black box warning (QT prolongation); activity in myeloma
- ZIO-101 preclinical data shows wide therapeutic window confirmed in phase I study
- Phase I trials:
  - Dosing: 50x inorganic arsenic dose
  - Wider therapeutic window likely enhance treatment opportunities



# ZIO-101: Clinical Trial Status

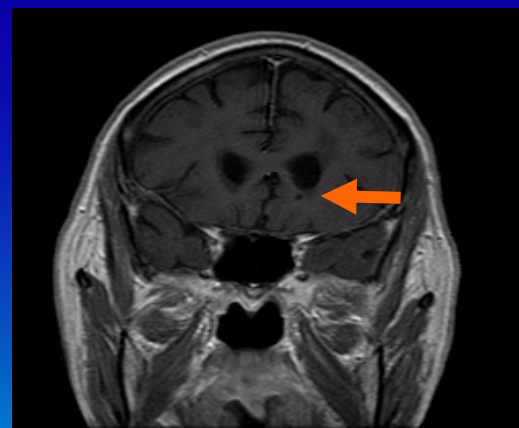
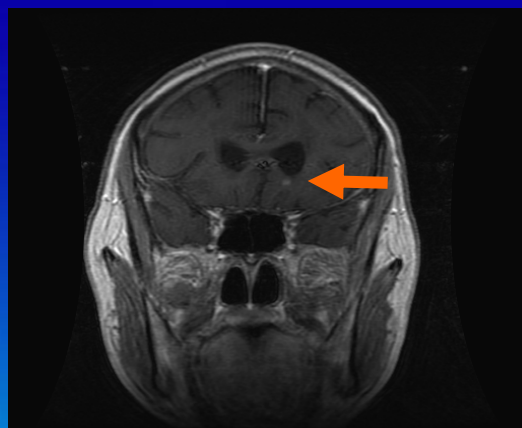
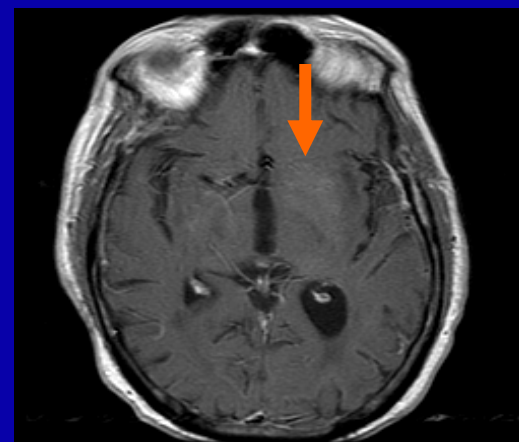
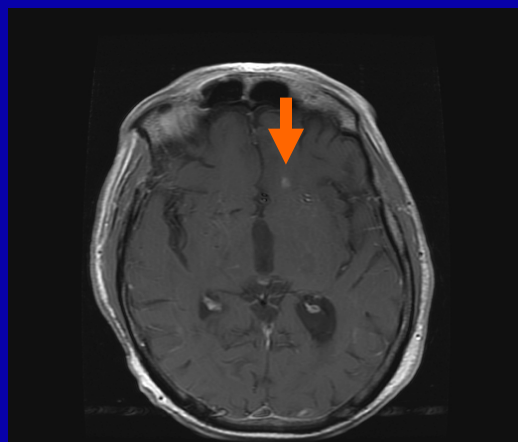
---

- Phase I/II in advanced myeloma
- Phase I in advanced cancers and leukemia
  - Interim results show early clinical activity and patient benefit
    - Solid tumors:
      - 5 patients with ongoing stable disease
      - 1 patient with mixed response
    - AML:
      - 4 patients with anti-leukemia effect
- Exploring oral dosing preclinically



# ZIO-101: Early Activity Results

---



Baseline

Post treatment



ZIOPHARM

# ZIO-101: Expected Registration Pathway

---

- Advanced myeloma
  - Phase I and II in US, Canada, UK
  - Expanded phase II study
  - Initiate pivotal trial 2007
- Other hematological and solid tumors
  - Phase II studies



# ZIO-101: Market Opportunity - Myeloma

---

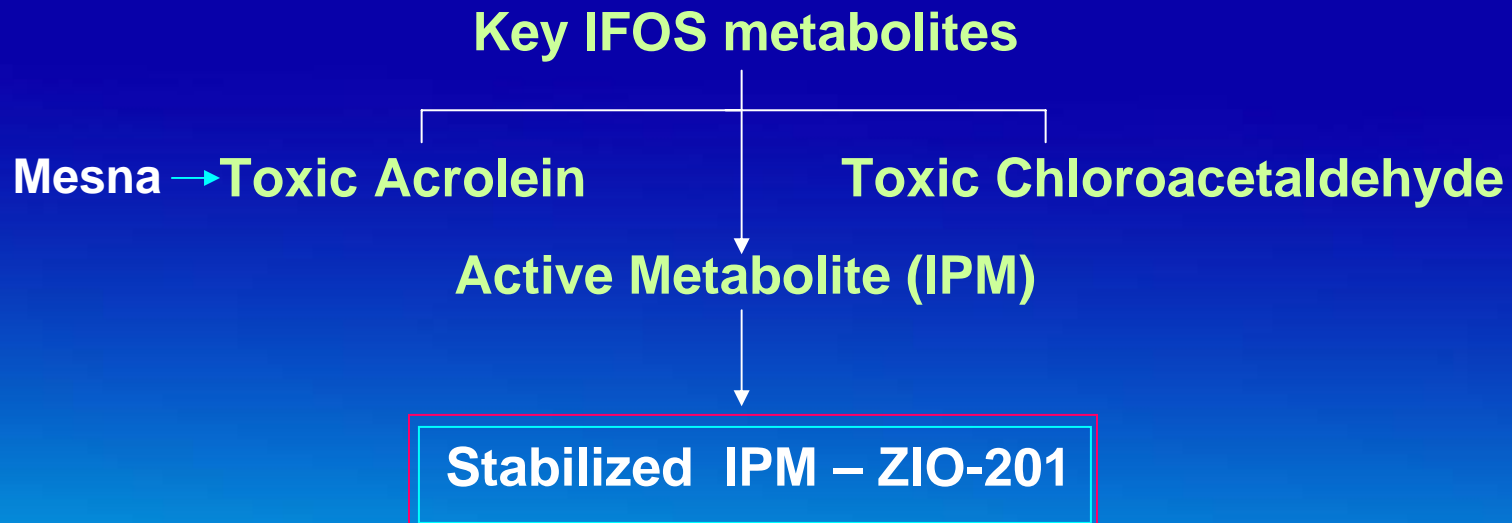
- Incidence: 17,000\* patients growing by ~1% each yr
- Prevalence: 65,000 patients / yr
- ZIO-101 expected U.S. launch 2009
  - AWP / patient / year \$15,000 – 25,000
  - Projected sales of >\$400MM

\*Estimate for 2009

# ZIO-201 – IPM

---

- Stabilized activated metabolite of ifosfamide - IFOS; (related to cyclophosphamide)
- Patent applications filed in U.S. and internationally
- Potentially safer and more active than IFOS



# ZIO-201: Related Molecule

---

- IFOS approved for testicular cancer; standard of care for sarcoma; ICE regimen for lymphoma
- ZIO-201 preclinical established benefit of stabilized active metabolite (IPM)
- ZIO-201 cross-links DNA differently, works in IFOS and cyclophosphamide resistant cells



# ZIO-201: Clinical Trial Status

---

- Phase I/II in advanced sarcoma
- Ongoing phase I in advanced cancers
  - One patient with stable disease for more than one year
  - Confirming MTD at 1.5 g/me<sup>2</sup>/cycle
  - Equivalent to high-dose IFOS (15-30 g/me<sup>2</sup>/cycle); bladder and neuro toxicities have **not** been observed with ZIO-201 (no mesna)
  - Exploring alternative dosing regimens
- Exploring oral dosing preclinically



# ZIO-201: Expected Registration Pathway

---

- Advanced sarcoma
  - Phase I/ II study
  - Expanded phase II study
  - Initiate pivotal trial 2007
- Hematological tumors and pediatric sarcoma
  - Phase I/II studies



# ZIO-201: Market Opportunity - Sarcoma

---

- Incidence: 9,420\* patients growing by ~1% each yr
- Prevalence: 60,000 patients / yr
- ZIO-201 expected U.S. launch 2009
  - AWP / patient / year \$20,000 – 40,000
  - Projected sales of >\$400MM

\*Estimate for 2009

# Expected Upcoming Developments

---

- 2006
  - √ Initiate ZIO-101 phase I/II trial in advanced myeloma
  - √ Initiate ZIO-201 phase I/II trial in advanced sarcoma
  - √ ZIO-201 preclinical data at BMT
  - √ ZIO-101 and ZIO-201/analogues preclinical data at AACR
  - ZIO-101/201 ongoing phase I data
  - Initiate additional phase II trials
  - Interim phase I/II and phase II data
  - Additional in-licensing
  - New exchange listing
- 2007
  - ZIO-101/201 phase II data
  - ZIO-101/201 pivotal trial initiation



# Management Team

---

- **Jon Lewis, MD, PhD**
  - CEO
- **Dick Bagley**
  - President, COO
- **Bob Gale, MD, PhD**
  - SVP, Research
- **Barbara Wallner, PhD**
  - SVP, Technical Operations and Chief Technical Officer
- **Brian Schwartz, MD**
  - SVP, Chief Medical Officer
- **Bob Morgan, JD**
  - VP, Regulatory Affairs and Quality, and Contract Counsel
- **Bob Newman**
  - VP, Business Operations



# Medical Advisory Board

---

Leaders in adult and pediatric oncology, solid and hematological tumors; translational medicine and drug development

- James Armitage, MD, *University of Nebraska Medical Center*
- Joseph Bertino, MD, *Cancer Institute of New Jersey*
- George Demetri, MD, *Dana Farber Cancer Institute*
- Lawrence Einhorn, MD, *Indiana Cancer Pavilion*
- Alan Houghton, MD, *Memorial Sloan Kettering Cancer Center*
- Alberto Pappo, MD, *Texas Children's Cancer Center*
- David Spriggs, MD, *Memorial Sloan Kettering Cancer Center*



ZIOPHARM

# ZIOPHARM Oncology, Inc.

---

- Two products engineered for better efficacy and safety
- Strong IP
- \$37MM financing to fund through to pivotal trials
- Combined >\$800 million sales potential with **ZIOPHARM** marketing North America
- Each product family with multiple development, registration, and marketing and/or out-licensing strategies
- Experienced management team with focus on execution



ZIOPHARM



**ZIOPHARM Oncology**

**BETTER CANCER MEDICINE**

[www.ziopharm.com](http://www.ziopharm.com)