# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**WASHINGTON, D.C. 20549**

# FORM 8-K

**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): February 10, 2016**

# KURA ONCOLOGY, INC.

**(Exact name of Registrant as Specified in Its Charter)**

| **Delaware** | **001-37620** | **61-1547851** |
|---|---|---|
| **(State or Other Jurisdiction of Incorporation)** | **(Commission File Number)** | **(IRS Employer Identification No.)** |

| | |
|---|---|
| **11119 N. Torrey Pines Rd, Suite 125**<br>**La Jolla, CA**<br>**(Address of Principal Executive Offices)** | **92037**<br>**(Zip Code)** |

**Registrant's Telephone Number, Including Area Code: (858) 500-8800**

**Not Applicable**
**(Former Name or Former Address, if Changed Since Last Report)**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instructions A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

**Item 7.01 Regulation FD Disclosure.**

Beginning on February 10, 2016, members of the management team of Kura Oncology, Inc. (the "Company") will be providing presentation materials (the "Presentation") to certain interested parties. A copy of the Presentation is attached hereto as Exhibit 99.1 and incorporated herein by reference.

The information contained in this Current Report on Form 8-K and in the accompanying Exhibit 99.1 are being furnished and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section and will not be incorporated by reference into any registration statement filed by the Company, under the Securities Act of 1933, as amended, unless specifically identified as being incorporated therein by reference. This Current Report on Form 8-K will not be deemed an admission as to the materiality of any information in this Current Report on Form 8-K that is being disclosed pursuant to Regulation FD.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

| Exhibit Number | Description |
|---|---|
| 99.1 | Presentation Materials of Kura Oncology, Inc. |

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

**KURA ONCOLOGY, INC.**

Date: February 10, 2016

By: /s/ Annette North

**Annette North**
**Senior Vice President and General Counsel**

Exhibit 99.1

KURA ONCOLOGY

Troy Wilson, Ph.D., J.D., President and CEO
February 2016

# FORWARD-LOOKING STATEMENTS

This presentation contains forward-looking statements. Such statements include, but are not limited to, statements regarding our research, pre-clinical and clinical development activities, plans and projected timelines for tipifarnib, and our other programs, plans regarding regulatory filings, our expectations regarding the relative benefits of our product candidates versus competitive therapies, and our expectations regarding the therapeutic and commercial potential of our product candidates. The words "believe," "may," "will," "estimate," "plan", "continue," "anticipate," "intend," "expect," "potential" and similar expressions (including the negative thereof), are intended to identify forward-looking statements. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Risks that contribute to the uncertain nature of the forward-looking statements include: our future preclinical studies and clinical trials may not be successful; the U.S. Food and Drug Administration (FDA) may not agree with our interpretation of the data from clinical trials of our product candidates; we may decide, or the FDA may require us, to conduct additional clinical trials or to modify our ongoing clinical trials; we may experience delays in the commencement, enrollment, completion or analysis of clinical testing for our product candidates, or significant issues regarding the adequacy of our clinical trial designs or the execution of our clinical trials may arise, which could result in increased costs and delays, or limit our ability to obtain regulatory approval; our product candidates may not receive regulatory approval or be successfully commercialized; unexpected adverse side effects or inadequate therapeutic efficacy of our product candidates could delay or prevent regulatory approval or commercialization; we may not be able to obtain additional financing. New risk factors and uncertainties may emerge from time to time, and it is not possible for Kura's management to predict all risk factors and uncertainties.

All forward-looking statements contained in this presentation speak only as of the date on which they were made. Other risks and uncertainties affecting us are described more fully in our filings with the Securities and Exchange Commission. We undertake no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

# CORPORATE OVERVIEW

**Development Strategy**

- Develop a diverse pipeline of targeted therapeutics for solid tumors and blood cancers
- Utilize precision medicine approaches to identify patients most likely to benefit from treatments
- Fast-to-market strategy; broaden indication set after clinical POC

**Pipeline**

- Lead candidate in 3 Phase 2 trials; additional Phase 2 trial planned
- Potential to initiate pivotal study in 2017/18
- Preclinical programs advancing; anticipate KO-947 IND 1H 2016

**Experienced Team**

- Key roles in oncology R&D roles at both biotech and pharma
- Members of team have worked together since 2007 at Intellikine and Wellspring Biosciences

**Solid Financials**

- $41.2M cash as of September 30, 2015*
- $50.3M net proceeds from public offering completed November 2015 (NASDAQ:KURA)

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* Includes Cash, Cash Equivalents, and Short-Term Investments

# DIVERSE DEVELOPMENT PIPELINE

| PROGRAM | LEAD OPTIMIZATION | PRECLINICAL | PHASE 1 | PHASE 2 |
|---|---|---|---|---|
| **Tipifarnib** Farnesyl Transferase Inhibitor | *HRAS* Mutant Solid Tumors | | | |
| | Peripheral T Cell Lymphoma | | | |
| | Lower Risk Myelodysplastic Syndromes | | | |
| **KO-947** ERK inhibitor | MAPK Pathway Tumors | | | |
| **Menin-MLL inhibitor** | Acute Leukemias | | | |

**MULTIPLE OPPORTUNITIES TO POSITION TIPIFARNIB FOR A REGISTRATION-ENABLING PHASE 3 PROGRAM IN 2017/2018**

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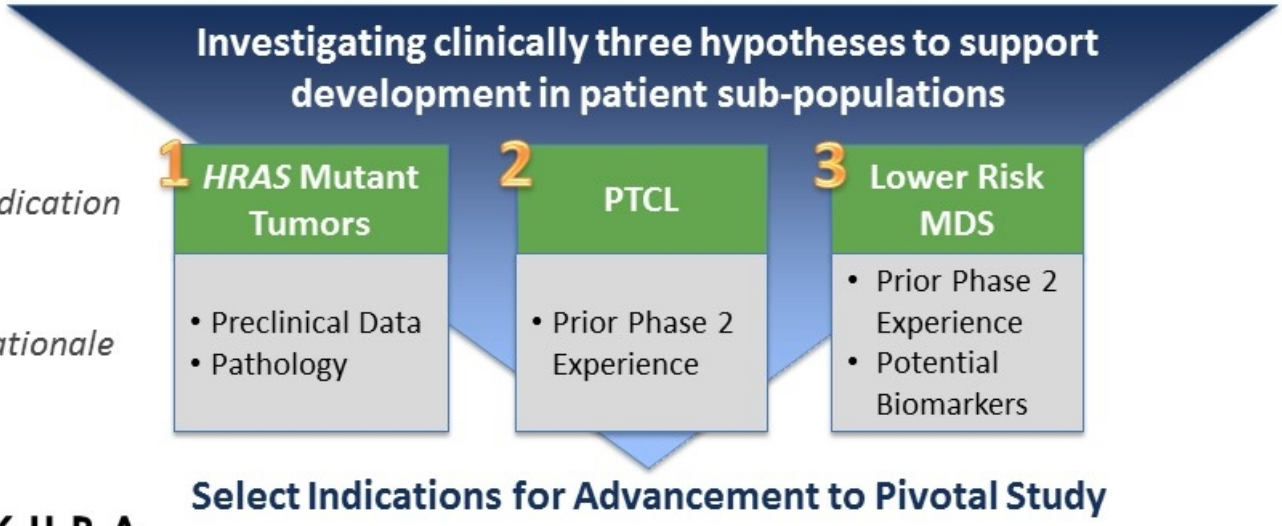
# TIPIFARNIB – LEAD PRODUCT CANDIDATE

- Licensed worldwide rights in oncology from Janssen
- Broad development program, which preceded precision medicine approach
  - Studied in > 5,000 patients
  - Generally well-tolerated
  - ORRs range from < 10-40% in unselected populations
  - Evidence of durable clinical benefit in patients

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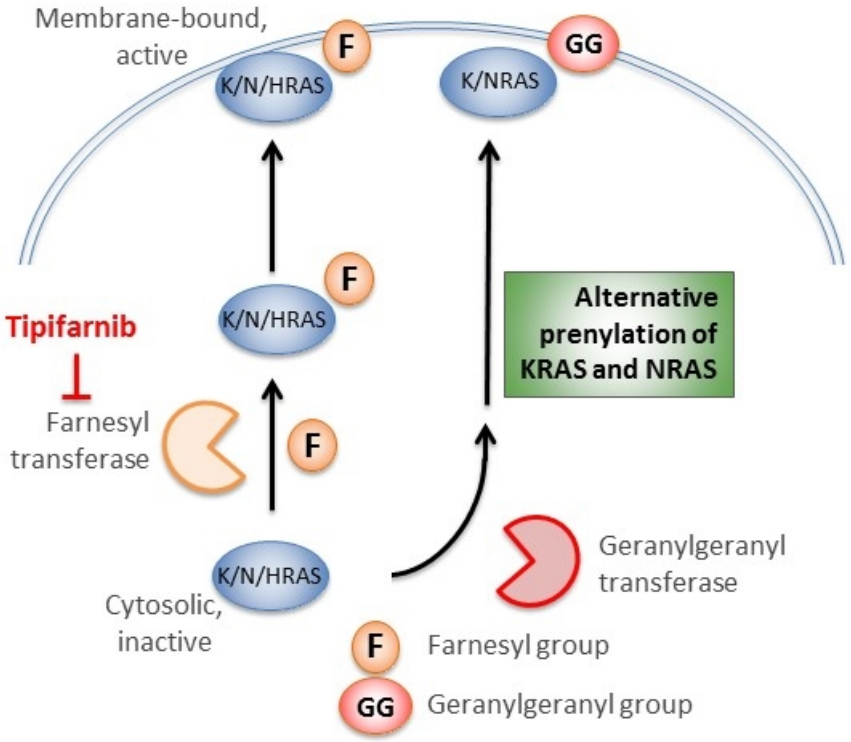
# 1 TIPIFARNIB MOA SUPPORTS DEVELOPMENT IN *HRAS* MUTANT SOLID TUMORS

- Tipifarnib is a farnesyl tranferase inhibitor (FTI)
- RAS signaling dependent on membrane localization
- FTIs block farnesylation and, thus, membrane localization
- Alternative modification by geranylgeranyl transferase enables KRAS/NRAS to "escape" FTIs
- HRAS solely dependent on farnesylation




**TIPIFARNIB INHIBITS HRAS SIGNALING**

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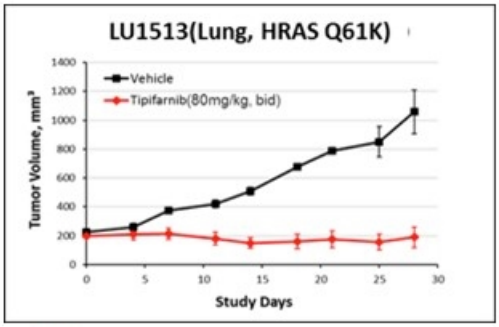
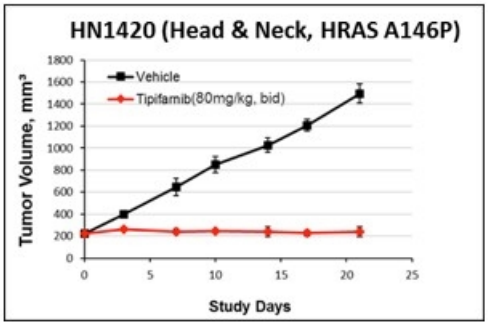
# 1 STRONG SCIENTIFIC RATIONALE TO TARGET *HRAS* MUTANT SOLID TUMORS

- HRAS has potential to be driver oncogene (Costello Syndrome, urothelial cancer)
- Tipifarnib is active in PDX models of *HRAS* mutant tumors
- Advances in technology permit patients with *HRAS* mutant tumors to be identified

**We are conducting a Kura-sponsored Phase 2 study (solid tumors) and supporting an Investigator-Sponsored Phase 2 study (urothelial cancer)**




| TISSUE | *HRAS* MUTATION FREQUENCY |
|---|---|
| Salivary gland | 15% |
| Urinary tract | 11% |
| Cervix | 9% |
| Upper aerodigestive tract | 9% |
| Prostate | 6% |
| Skin | 6% |
| Stomach | 4% |
| Testis | 4% |
| Thyroid | 3% |
| | |
| **Collective US Incidence** | **~ 8,000** |

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# 2 PHASE 2 ACTIVITY OF TIPIFARNIB HAS BEEN OBSERVED IN PERIPHERAL T-CELL LYMPHOMAS

- Tipifarnib was previously studied in a 93 patient Phase 2 trial of various relapsed/refractory lymphomas[1]
- High activity observed in third cohort – heavily pretreated patients with T-Cell and Hodgkin's Lymphoma
  - ORR: 31%
  - 81% of patients (29/36) had ≥ 4 prior therapies and 67% (24/36) prior SCT
- Safety findings across all Phase 2 patients (grade 3,4): 37% neutropenia, 32% thrombocytopenia, 11% anemia
- Potential to improve response and clinical benefit in 2nd line PTCL
- U.S. incidence ~ 5,000 patients

| Disease Indication | n | CR n (%) | PR n (%) | ORR (%) |
|---|---|---|---|---|
| Overall | 36 | 6 (17) | 5 (14) | 31% |
| Hodgkin Lymphoma | 19 | 2 (11) | 2 (11) | 21% |
| Mycosis Fungoides | 4 | 0 (0) | 2 (50) | 50% |
| **Peripheral T-Cell Lymphoma** | **8** | **3 (38)** | **1 (13)** | **50%** |
| Anaplastic Large Cell Lymphoma | 5 | 1 (20) | 0 (0) | 20% |

[1] Study conducted at Mayo Clinic and U. Iowa

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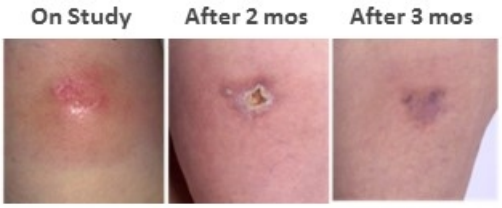
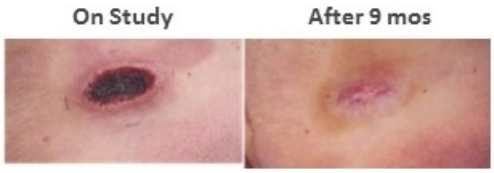
# 2 TIPIFARNIB ACTIVITY COMPARES FAVORABLY TO CURRENT STANDARDS OF CARE




Subcutaneous Panniculitis-like T-Cell Lymphoma (SPTCL)




Mycosis Fungoides (CTCL)

| | N | Prior Therapy median | CR (%) | ORR (%) | Median PFS/TTP (mos) | Median OS (mos) |
|---|---|---|---|---|---|---|
| Beleodaq® (belinostat) for injection | 120 | 2 | 11 | 26 | 1.6 | 7.9 |
| ISTODAX® (romidepsin) for injection | 130 | 2 | 15 | 25 | 4.0 | 11.3 |
| FOLOTYN | 109 | 3 | 8 | 27 | 3.5 | 14.5 |
| | | | | | | |
| **Tipifarnib (T-cell / Hodgkin's Lymphoma)** | **36** | **≥ 4** | **17[2]** | **31** | **3.2** | **19.7** |

[1] Table lists data from separate studies; not head to head comparisons
[2] Three CRs (37.5%) and 1 PR in 8 PTCL patients

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# 3 STRONG RATIONALE FOR INVESTIGATING TIPIFARNIB IN MYELODYSPLASTIC SYNDROMES

- MDS interferes with normal stem cell differentiation, resulting in cytopenias and carries a risk for transformation into AML
- Represents a significant unmet medical need
  - U.S. incidence of 13,000; prevalence of > 60,000 cases
  - 75% of patients (~ 9,750) comprise lower risk MDS
- Previous Phase 2 clinical data demonstrates tipifarnib is active in MDS
- We have identified potential biomarkers that may allow us to select patients likely to receive benefit

**We are planning a Phase 2 study to investigate tipifarnib activity in patients with lower risk MDS, with a potential for a biomarker-driven, registrational study.**

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# 3 OPPORTUNITY WITH MYELODYSPLASTIC SYNDROMES: PRIOR CLINICAL EXPERIENCE

- Tipifarnib has shown promising activity in intermediate/high-risk MDS in a previous Phase 2 study (sponsored by Johnson & Johnson)

| **Study INT-28: Intermediate/High Risk MDS*** **Previous Phase 2 study sponsored by Johnson & Johnson** | **Overall (N = 82)** |
|---|---|
| ORR (CR+HI) | 26 (31.7%) |
| Complete Response (CR) | 12 (14.6%) |
| Hematologic Improvement (HI) | 14 (17.1%) |

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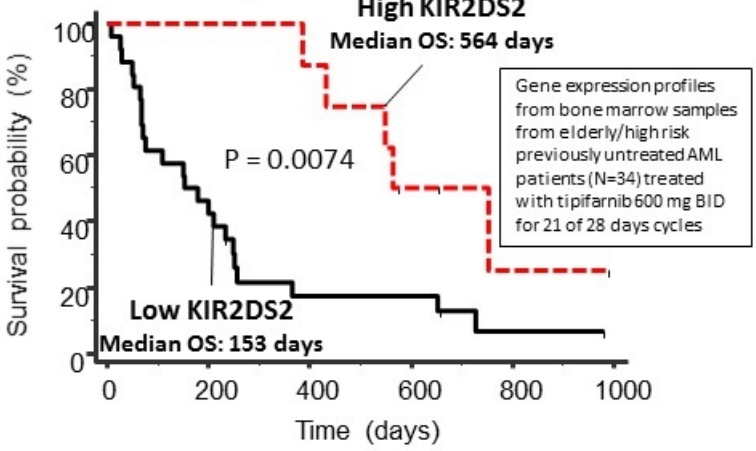
*Defined by International Prognostic Scoring System (IPSS)

# 3 EXPRESSION OF KIR2DS2 CORRELATES WITH TIPIFARNIB CLINICAL BENEFIT IN AML

**Tipifarnib Treated Patients (n=34)**

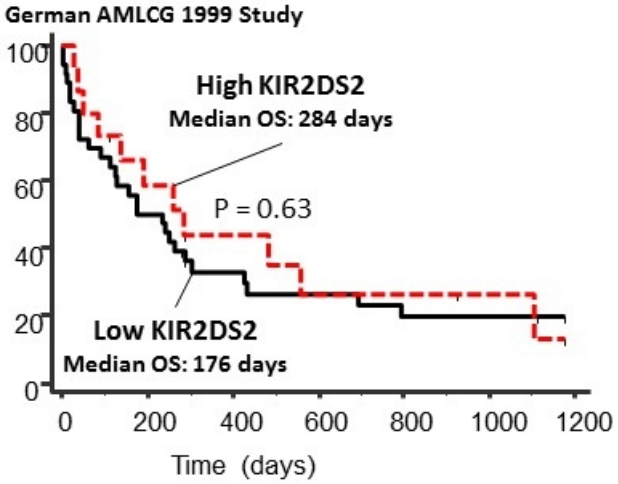
**NCI CTEP-20 Study**




Gene expression profiles from bone marrow samples from elderly/high risk previously untreated AML patients (N=34) treated with tipifarnib 600 mg BID for 21 of 28 days cycles

**Chemotherapy Treated Patients (n=51)**

**German AMLCG 1999 Study**




- High expression KIR2DS2 correlated with CR rate and OS in tipifarnib-treated AML patients; no correlation in chemo treated patients
- Expression of KIR2DS2 has been shown to predispose patients to the development of MDS
- Activating KIRs are known to signal in part through the RAS pathway

This supports the hypothesis that KIR2DS2 may be a potential biomarker to select patients with hematologic malignancies likely to receive benefit from tipifarnib.

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# INVESTIGATING MULTIPLE CLINICAL HYPOTHESES

**Identify Therapeutic Opportunities**
**Facilitate Rapid & Efficient Clinical Validation**

| | *HRAS* Mutant Tumors | | | PTCL | Lower Risk MDS* |
|---|---|---|---|---|---|
| **Subjects** | Thyroid n=18 | Solid n=18 | Urothelial n=18 | n=18 (Potential for expansion to n=30) | n = 54 |
| **1° Endpoint** | ORR (RECIST v1.1) | | | ORR (IWC) | RBC transfusion independence |
| **Rationale** | Preclinical data Pathology series (urothelial) | | | Phase 2 clinical experience | Phase 2 clinical experience/Patient Biomarker Analysis |
| **Biomarkers** | Documented *HRAS* mutations | | | Exploratory | NK cell markers including KIR2DS2 |
| **Estimated U.S. Incidence** | 8,000 | | | 5,000 | 9,750 |

* Proposed clinical plan

**Select Indications for Advancement to Pivotal Study**

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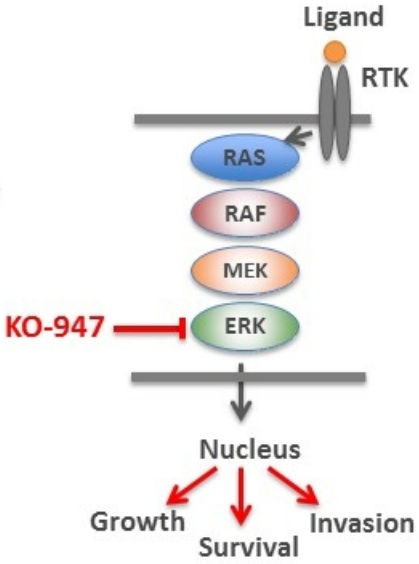
# PRECLINICAL ERK INHIBITOR – KO-947

- ATP active-site inhibitor of ERK
- Targets well-validated pathway that has led to multiple approved targeted oncology agents
- Aberrant signaling caused by activating mutations (KRAS, NRAS, BRAF) associated with numerous tumor types
- BRAF and MEK inhibitors have demonstrated high response rates; acquired resistance limits effectiveness
- Potential to address resistance mutations and other limitations of upstream targets
- Discovered and developed by Kura Oncology team at Araxes/Wellspring; acquired through asset purchase

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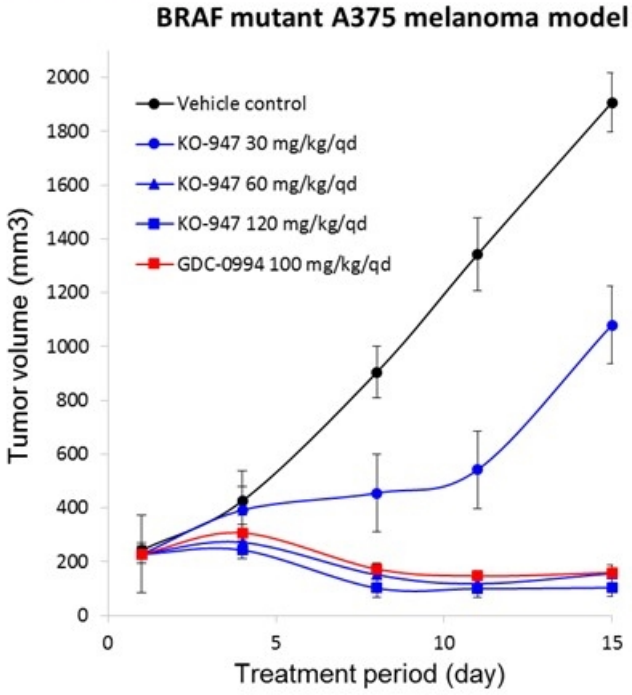
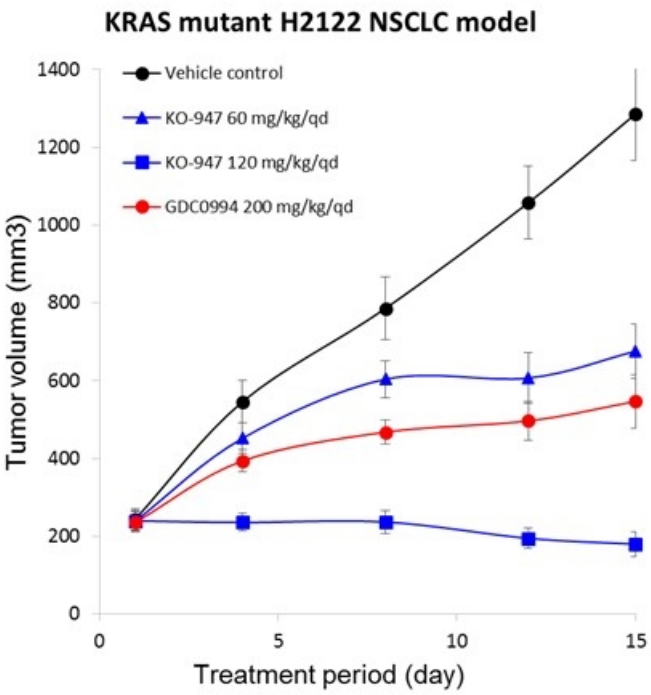
# KO-947: STRONG ACTIVITY IN *BRAF* AND *KRAS* MUTANT TUMOR MODELS




- KO-947 induced tumor regression in BRAF and KRAS mutated tumor models
- KO-947 compares favorably to clinical-stage reference compound, GDC-0994

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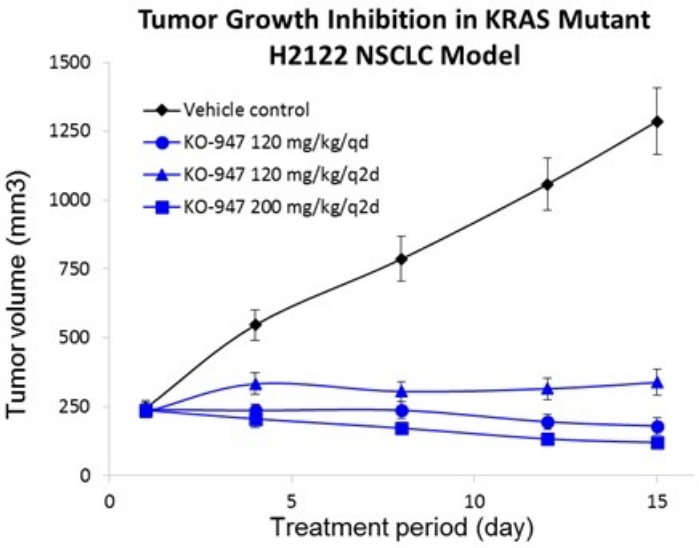
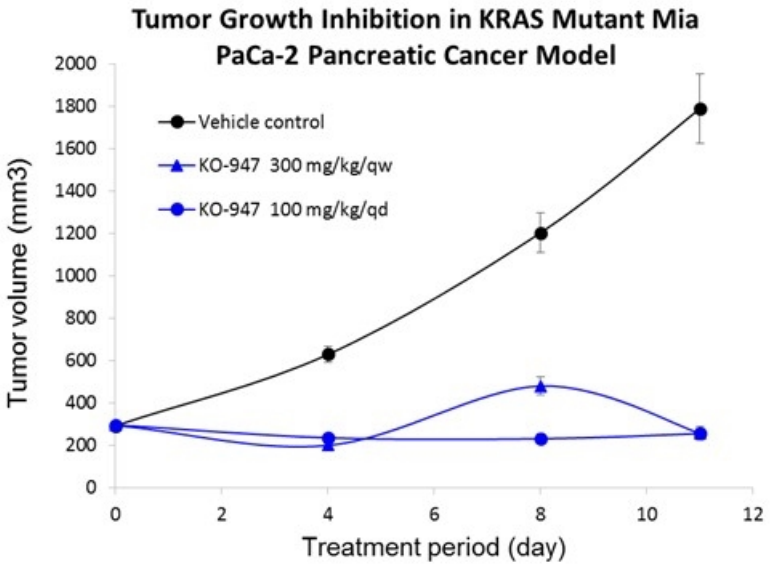
# KO-947: STRONG ACTIVITY WITH INTERMITTENT DOSING SCHEDULE




- KO-947 displayed comparable anti-tumor activity with intermittent dosing schedule
- Intravenous administration has potential to improve exposure and tolerability

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# KO-947: RATIONALE FOR FURTHER STUDY

**Development Plans**

- IND-enabling studies ongoing
- Translational research evaluating potential lead indications
- IV route of administration selected for initial clinical study
- Opportunity to advance oral program to broaden indication set

**Anticipated Milestones**

| | |
|---|---|
| • IND submission | 1H 2016 |
| • Initiate Phase 1 study | 2H 2016 |

**U.S. Commercial Opportunity**

- *KRAS* mutant tumors incidence
  - Pancreatic cancer: 45,000
  - Colorectal cancer: 53,000
  - Non-small cell lung cancer: 23,000
- *BRAF* mutant malignant melanoma incidence: 5,000

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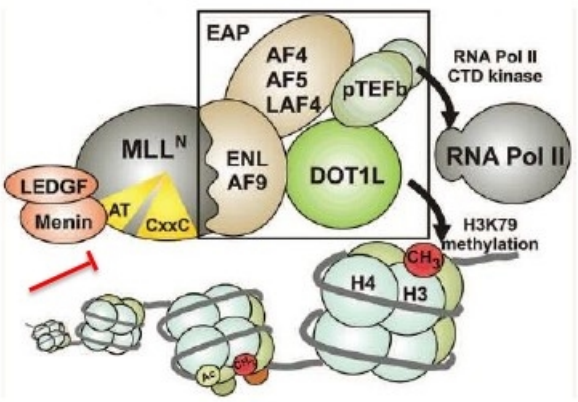
# MENIN-MLL INHIBITOR PROGRAM

- Chromosomal translocations of the *MLL* gene play a causative role in the onset, development and progression of a subset of acute leukemias
- Potential first-in-class program targeting the menin-MLL interaction for treatment of MLL-rearranged and MLL-PTD AML and ALL




- 3,200 patients with MLL-rearranged and MLL-PTD in the U.S.
- Opportunities to target menin overexpression in additional tumor types
- Licensed worldwide rights from University of Michigan
- Currently in lead optimization; development candidate anticipated 2H 2016

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# DIVERSE PIPELINE WITH POTENTIAL FOR NEAR-TERM VALUE-CREATING MILESTONES

| PROGRAM | EVENT | ANTICIPATED TIMING |
|---|---|---|
| **Tipifarnib** | Phase 2 clinical trial in *HRAS* mutant solid tumors | Ongoing |
| **Tipifarnib** | Phase 2 clinical trial in PTCL | Ongoing |
| **Tipifarnib** | Phase 2 IST in *HRAS* mutant urothelial cancer | Ongoing |
| **Tipifarnib** | Initiate Phase 2 clinical study in lower risk MDS | 1H 2016 |
| **KO-947** | IND submission | 1H 2016 |
| **KO-947** | Initiate Phase 1 clinical trial | 2H 2016 |
| **Tipifarnib** | Topline data from Phase 2 study in *HRAS* mutant tumors | 2H 2016 |
| **Menin-MLL** | Nomination of development candidate | 2H 2016 |
| **Tipifarnib** | Topline data from Phase 2 study in low-risk MDS | 1H 2017 |
| **Tipifarnib** | Topline data from Phase 2 clinical trial in PTCL | 2H 2017 |

# EXPERIENCED MANAGEMENT TEAM

| | |
|---|---|
| **Troy Wilson, Ph.D., J.D.** | Chief Executive Officer |
| **Yi Liu, Ph.D.** | Chief Scientific Officer |
| **Pingda Ren, Ph.D.** | SVP, Chemistry and Pharm. Sciences |
| **Antonio Gualberto, M.D., Ph.D.** | Chief Medical Officer |
| **Heidi Henson, CPA** | Chief Financial Officer |
| **Annette North, LLB** | SVP and General Counsel |

# BOARD AND ADVISORS

## BOARD OF DIRECTORS

| | |
|---|---|
| **Faheem Hasnain** | Former President and CEO, Receptos, Inc. |
| **Robert Hoffman** | SVP Finance and CFO, AnaptysBio, Inc. |
| **Thomas Malley** | Mossrock Capital |
| **Troy Wilson, Ph.D., J.D.** | CEO and President, Kura Oncology, Inc. |

## SCIENTIFIC ADVISORS

| | |
|---|---|
| **Kevan Shokat, Ph.D.** | Professor and Chairman, Dept. Cellular & Molecular Pharmacology, UCSF |
| **Frank McCormick, Ph.D., FRS** | Director Emeritus of the UCSF Helen Diller Cancer Center and Professor, UCSF |
| **Neal Rosen, M.D., Ph.D.** | Director of the Center for Molecular Therapeutics at Memorial Sloan-Kettering Cancer Center |
| **Sir Simon Campbell, CBE, FRS** | Former Senior VP Worldwide Discovery & Medicinal R&D Europe at Pfizer |
| **Jeffrey Engelman, M.D., Ph.D.** | Director, Center for Thoracic Cancers, Massachusetts General Hospital Cancer Center |

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* Includes Cash, Cash Equivalents, and Short-Term Investments


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