KRYS TAL-1: Updated Safety and Efficacy Data With Adagrasib (MRTX849) in NSCLC With KRAS\textsuperscript{G12C} Mutation From a Phase 1/2 Study

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Disclosures

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• Other:
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KRASG12C mutations act as oncogenic drivers and occur in approximately 14% of NSCLC (adenocarcinoma), 3-4% of CRC, and 1-2% of several other cancers1-3.

The KRAS protein cycles between GTP-On and GDP-Off states and has a protein resynthesis half-life of ~24 h4,5.

Adagrasib is a covalent inhibitor of KRASG12C that irreversibly and selectively binds KRASG12C in its inactive, GDP-bound state6.

Adagrasib was optimized for desired properties of a KRASG12C inhibitor:
- Potent covalent inhibitor of KRASG12C (cellular IC50: ~5 nM)
- High selectivity (>1000X) for the mutant KRASG12C protein vs wild-type KRAS
- Favorable PK properties, including oral bioavailability, long half-life (~24 h), and extensive tissue distribution

Hypothesis: Maintaining continuous exposure of adagrasib above a target threshold enables inhibition of KRAS-dependent signaling for the complete dose interval and maximizes depth and duration of antitumor activity.

**KRYS0TAL-1 (849-001) Study Design**

**Key Eligibility Criteria**

**Up to n=391**

- Solid tumor with KRAS<sup>G12C</sup> mutation
- Unresectable or metastatic disease
- Progression on or following treatment with a PD-1/L1 inhibitor following or in combination with chemotherapy (NSCLC)<sup>a</sup>
- Treated and/or stable brain metastases<sup>b</sup>

**Phase 1 Dose Escalation**
- 150 mg QD
- 300 mg QD
- 600 mg QD
- 1200 mg QD
- 600 mg BID

**Expansion**

**Phase 1B Dose Expansion and Combination**
- **Adagrasib monotherapy NSCLC**
  - n=18 (Phase 1/1b)
  - Adagrasib + pembrolizumab in NSCLC
  - Adagrasib + afatinib in NSCLC
  - Adagrasib + cetuximab in CRC

**Phase 2 Monotherapy Treatment**

- NSCLC<sup>c</sup> n=61
- CRC
- Other solid tumors

**Phase 1 Endpoints**
- Primary: Safety, MTD, PK, RP2D
- Secondary: Objective Response (RECIST 1.1), DOR, PFS, OS

**Phase 2 Endpoints**
- Primary: ORR (RECIST 1.1)
- Secondary: Safety

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<sup>a</sup>Applies to the majority of NSCLC cohorts. <sup>b</sup>Most cohorts allow patients with brain metastases if adequately treated and stable; additional phase 1/1b cohort allows limited brain metastases.

<sup>c</sup>Primary NSCLC cohort eligibility based on a tissue test; KRAS<sup>G12C</sup> testing for entry was performed locally or centrally using a sponsor pre-approved test. ClinicalTrials.gov. NCT03785249.

- Previously reported data from Phase 1 demonstrated clinical activity with adagrasib (MRTX849) in patients with pretreated KRAS<sup>G12C</sup> NSCLC and CRC
- 600 mg BID was chosen as the RP2D
- Here we report data for 79 patients evaluating adagrasib 600 mg BID in patients with previously treated NSCLC in Phase 1/1b (n=18, median follow-up, 9.6 mo) and Phase 2 (n=61); pooled (n=79) median follow-up, 3.6 mo
- Data cut-off date: 30 August 2020

Presented at the 32nd EORTC-NCI-AACR Symposium, October 24-25, 2020

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## Patient Demographics and Baseline Characteristics: NSCLC

<table>
<thead>
<tr>
<th></th>
<th>Phase 1/1b 600 mg BID (n=18)</th>
<th>Phase 1/1b and 2 600 mg BID (n=79)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Median age, y (range)</strong></td>
<td>65 (40-76)</td>
<td>65 (25-85)</td>
</tr>
<tr>
<td><strong>Female, n (%)</strong></td>
<td>11 (61%)</td>
<td>45 (57%)</td>
</tr>
<tr>
<td><strong>Race, n (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>15 (83%)</td>
<td>67 (85%)</td>
</tr>
<tr>
<td>Black</td>
<td>3 (17%)</td>
<td>5 (6%)</td>
</tr>
<tr>
<td>Asian</td>
<td>0 (0%)</td>
<td>5 (6%)</td>
</tr>
<tr>
<td>Other</td>
<td>0 (0%)</td>
<td>2 (3%)</td>
</tr>
<tr>
<td><strong>ECOG PS, n (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>8 (44%)</td>
<td>17 (22%)</td>
</tr>
<tr>
<td>1</td>
<td>10 (56%)</td>
<td>62 (78%)</td>
</tr>
<tr>
<td><strong>Current/former smokers</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>16 (89%)</td>
<td>75 (95%)</td>
</tr>
<tr>
<td><strong>Nonsquamous histology, n (%)</strong></td>
<td></td>
<td>76 (96%)</td>
</tr>
<tr>
<td><strong>Prior lines of anticancer therapy(^a), median (range)</strong></td>
<td>3 (1-9)</td>
<td>2 (1-9)</td>
</tr>
<tr>
<td><strong>Prior anti-PD-1/L1 inhibitor, n (%)</strong></td>
<td>16 (89%)</td>
<td>73 (92%)</td>
</tr>
</tbody>
</table>

\(^a\)Phase 2 patients with NSCLC received prior treatment with platinum regimens. Data as of 30 August 2020. Pooled includes NSCLC Phase 1/1b and Phase 2 600 mg BID.
Adagrasib at 600 mg BID Exhibits Favorable PK Properties; Exposure Maintained Above Target Plasma Thresholds Throughout Full Dosing Interval

PK Properties Summary:
- \( C_{\text{ave}} \) of 2.63 \( \mu \)g/mL is 2-5-fold above target threshold for full dose interval
- \( C_{\text{ave}} \) PK parameter best matched to nonclinical antitumor activity
- Low peak to trough ratio at steady state (~1.27)
- \( t_{1/2} \) ~ 24 hours
- Extensive volume of distribution predicted based on nonclinical studies

Data as of 18 March 2020.

\( a \) Includes 14 NSCLC, 1 CRC, and 2 appendiceal patients from Phase 1/1b.

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## Incidence of Treatment-Related Adverse Events

<table>
<thead>
<tr>
<th>TRAEs&lt;sup&gt;b,c&lt;/sup&gt;, %</th>
<th>Any grade</th>
<th>Grades 3-4</th>
<th>Grade 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any TRAEs</td>
<td>85%</td>
<td>30%</td>
<td>2%</td>
</tr>
<tr>
<td><strong>Most frequent TRAEs&lt;sup&gt;a,d&lt;/sup&gt;, %</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nausea</td>
<td>54%</td>
<td>2%</td>
<td>0%</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>51%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Vomiting</td>
<td>35%</td>
<td>2%</td>
<td>0%</td>
</tr>
<tr>
<td>Fatigue</td>
<td>32%</td>
<td>6%</td>
<td>0%</td>
</tr>
<tr>
<td>Increased ALT</td>
<td>20%</td>
<td>5%</td>
<td>0%</td>
</tr>
<tr>
<td>Increased AST</td>
<td>17%</td>
<td>5%</td>
<td>0%</td>
</tr>
<tr>
<td>Increased blood creatinine</td>
<td>15%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Decreased appetite</td>
<td>15%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>QT prolongation</td>
<td>14%</td>
<td>3%</td>
<td>0%</td>
</tr>
<tr>
<td>Anemia</td>
<td>13%</td>
<td>2%</td>
<td>0%</td>
</tr>
</tbody>
</table>

- Grade 5 TRAEs included pneumonitis in a patient with recurrent pneumonitis (n=1) and cardiac failure (n=1)
- 7.3% of TRAEs led to discontinuation

<sup>a</sup>Includes patients pooled from Phase 1/1b and Phase 2 NSCLC (n=79), and CRC and Phase 2 other tumor cohorts (n=31).  
<sup>b</sup>Includes events reported between first dose and 30 August 2020.  
<sup>c</sup>The most common treatment-related SAEs reported (2 patients each) reported were diarrhea (grade 1, grade 2) and hyponatremia (both grade 3).  
<sup>d</sup>Occurred in ≥10%.

Data as of 30 August 2020.
# Adagrasib in Patients With NSCLC: ORR in Pooled Dataset

<table>
<thead>
<tr>
<th>Efficacy Outcome^a, n (%)</th>
<th>Phase 1/1b, NSCLC 600 mg BID (n=14)</th>
<th>Phase 1/1b and 2, NSCLC 600 mg BID (n=51)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Objective Response Rate</strong></td>
<td>6 (43%)</td>
<td>23 (45%)^b</td>
</tr>
<tr>
<td><strong>Best Overall Response</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Complete Response (CR)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Partial Response (PR)</td>
<td>6 (43%)</td>
<td>23 (45%)</td>
</tr>
<tr>
<td>Stable Disease (SD)</td>
<td>8 (57%)</td>
<td>26 (51%)</td>
</tr>
<tr>
<td>Progressive Disease (PD)</td>
<td>0 (0%)</td>
<td>1 (2%)</td>
</tr>
<tr>
<td>Not Evaluable (NE)</td>
<td>0 (0%)</td>
<td>1 (2%)^c</td>
</tr>
<tr>
<td><strong>Disease control</strong></td>
<td>14 (100%)</td>
<td>49 (96%)</td>
</tr>
</tbody>
</table>

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^aBased on investigator assessment of the clinically evaluable patients (measurable disease with ≥1 on-study scan); 14/18 patients (Phase 1/1b) and 51/79 patients (Phase 1/1b and 2 pooled) met these criteria. ^bAt the time of the 30 August 2020 data cut off, 5 patients had unconfirmed PRs. All 5 were confirmed by scans that were performed after the 30 August 2020 data cut off. ^cOne patient had tumor reimaging too early for response assessment.

Data as of 30 August 2020. Pooled includes NSCLC Phase 1/1b and Phase 2 600 mg BID.
Adagrasib 600 mg BID in Patients With NSCLC: Best Tumor Change From Baseline

- Clinical benefit (DCR) observed in 96.1% (49/51) of patients

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4Two timepoint assessments of CR were separated by recurrent disease associated with treatment interruption due to hypoxia; this patient remains on treatment and in two consecutive scans (1 after August 30 data cutoff) demonstrated 100% tumor regression in target and non-target lesions after resuming treatment.

Data as of 30 August 2020. Pooled includes NSCLC Phase 1/1b and Phase 2 600 mg BID.
Adagrasib 600 mg BID in Patients With NSCLC: Treatment Duration and Change in Tumor Burden

Data as of 30 August 2020

- Median follow-up, 9.6 mo
- 5 of the 6 responders remain on treatment; treatment ongoing >11 mo for the majority of patients with responses (4/6)
- Median time to response, 1.5 mo

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**Duration of Treatment in Patients With NSCLC Treated With Adagrasib 600 mg BID in Pooled Dataset**

- Median follow-up, 3.6 mo
- Median time to response, 1.5 mo
- 83% (19/23) of responders have not progressed and remain on study
- 65% (33/51) of patients remain on treatment

Data as of 30 August 2020. Pooled includes NSCLC Phase 1/1b and Phase 2 600 mg BID.

Presented at the 32nd EORTC-NCI-AACR Symposium, October 24-25, 2020
Adagrasib Penetrates the Brain/CSF and Results in Tumor Regression in a Preclinical Model\textsuperscript{a}

- Adagrasib demonstrates dose-dependent brain and CSF exposure in preclinical studies.
- A single 100 mg/kg oral dose in mice results in brain concentrations exceeding the cellular IC\textsubscript{50} of adagrasib.
- Plasma levels achieved at 100 mg/kg BID in mice are comparable to levels achieved at a 600 mg BID human dose and results in near complete tumor regression in LU99Luc KRAS\textsuperscript{G12C} tumors.

\textsuperscript{a}Data on file, Mirati Therapeutics, Inc.

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Mean Plasma and Brain Concentrations of Adagrasib After a Single 100 mg/kg Oral Dose in Mice

- Mean plasma
- Mean brain

Cellular IC\textsubscript{50} = 1000 ng/mL

K\textsubscript{p,uu} = 0.4 (1 h)

**LU99Luc KRAS\textsuperscript{G12C} Brain Metastases Model**

- **Vehicle**: No significant change in tumor size.
- **Adagrasib 100 mg/kg BID**: Near complete tumor regression observed.

Presented at the 32nd EORTC-NCI-AACR Symposium, October 24-25, 2020.
Patient Case: Patient With Brain Metastasis and KRAS<sup>G12C</sup> Mutation

Baseline

Adagrasib 600 mg BID, Cycle 7
PR, (-67%)

- 77-year-old female previous smoker
- NSCLC diagnosed, April 2019
- Only mutation identified by NGS panel: KRAS<sup>G12C</sup>
- Treatment history
  - Carboplatin, pemetrexed, pembrolizumab, May-July 2019
  - Pemetrexed maintenance, August-December 2019
  - Left frontal brain met radiation, November 2019
  - Pembrolizumab maintenance, January-February 2020
  - Pemetrexed, March 2020
  - Left and right cerebellar radiation, March 2020
- Patient started adagrasib 600 mg BID, May 2020
- Metastases were in the lung and liver and an unirradiated brain lesion in the right middle frontal gyrus
- TRAEs
  - Grade 1 nausea, vomiting, diarrhea, dysphagia, anemia, rash, and thigh discomfort
- Currently in cycle 7

Data as of 25 September 2020.
Patient Case: Response in NSCLC Harboring KRAS\textsuperscript{G12C} and STK11 Co-Mutations

Baseline

Adagrasib 600 mg BID, Cycle 6
PR (-56%)

Adagrasib 600 mg BID, Cycle 10
PR (-59%)

• 53-year-old male former smoker; NSCLC diagnosed, December 2018
• KRAS\textsuperscript{G12C} and STK11\textsuperscript{N41*} mutations detected by NGS
• Treatment history
  – Radiotherapy to brain, December 2018
  – Carboplatin, pemetrexed, pembrolizumab, January-April 2019 with BOR of SD
  – Radiotherapy to brain, March-April 2019
  – Pemetrexed with pembrolizumab as continuation maintenance through September 2019
  – LMB-100 (investigational agent) with pembrolizumab, October-December 2019
• Patient started adagrasib 600 mg BID in February 2020
• No TRAEs
• Patient remains on study

Data as of 05 October 2020.
## Preliminary Exploratory Correlative Analysis of Co-Mutations Including STK11 With KRAS\(^{G_{12C}}\) and Response Rate in Patients with NSCLC Treated with Adagrasib

### Response Rate, %

<table>
<thead>
<tr>
<th>Mutation</th>
<th>Response Rate, %</th>
<th>Number of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>STK11</td>
<td>64%</td>
<td>9/14</td>
</tr>
<tr>
<td>KEAP1</td>
<td>33%</td>
<td>10/30</td>
</tr>
<tr>
<td>TP53</td>
<td>36%</td>
<td>5/14</td>
</tr>
<tr>
<td>KRAS(^{G_{12C}}) (all patients)</td>
<td>48%</td>
<td>14/29</td>
</tr>
<tr>
<td></td>
<td>45%</td>
<td>23/51</td>
</tr>
<tr>
<td></td>
<td>38%</td>
<td>9/24</td>
</tr>
<tr>
<td></td>
<td>33%</td>
<td>11/23</td>
</tr>
<tr>
<td></td>
<td>36%</td>
<td>10/30</td>
</tr>
</tbody>
</table>

### Best Tumor Change From Baseline for PatientsHarboring KRAS\(^{G_{12C}}\) and STK11 Co-mutations

- Baseline NGS reports reviewed for exploratory correlative analysis for all NSCLC patients with available mutation data\(^a\)
- **64% ORR** in patients with tumors harboring STK11 and KRAS\(^{G_{12C}}\) mutations
- No apparent trend with KEAP1, TP53, or other common mutations and response rate

\(^a\)Analysis includes key mutations detected at baseline in tumor and/or plasma that commonly occur with KRAS\(^{G_{12C}}\). Mutations included as positive include, nonsense, frameshift, splice site, and recurrent mutations predicted to have deleterious impact, and excluded VUS.

Data as of 30 August 2020. Based on unaudited data.

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Conclusions

• Adagrasib is a KRAS$^{G12C}$-selective covalent inhibitor with a long half-life, and extensive predicted target coverage throughout the dosing interval
• Adagrasib is well tolerated
• Adagrasib provides durable benefit to patients with NSCLC harboring KRAS$^{G12C}$ mutations
  • Durable responses were observed
  • Broad disease control rate was observed
• In a preliminary exploratory genomic analysis, ORR was higher in patients with tumors harboring KRAS$^{G12C}$ and STK11 co-mutations
• Pembrolizumab combination (NSCLC) arm has cleared the DLT observation period and enrollment in Phase 1b expansion at full dose of each agent is ongoing
• Combination clinical trials are enrolling or planned in NSCLC with afatinib, TNO155 (SHP2-inhibitor), and palbociclib

Responses observed in CRC (n=3/18; 17%), and in patients with pancreatic, ovarian, and endometrial cancers, and cholangiocarcinoma

See Johnson ML et al., abstract LBA-04.

aClinicalTrials.gov. NCT03785249. bClinicalTrials.gov. NCT04330664.
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Abbreviations

BID = twice daily
C_{ave} = average drug plasma concentration
CBR = clinical benefit rate
CRC = colorectal cancer
CSF = cerebrospinal fluid
DCR = disease control rate
DLT = dose limiting toxicity
DOR = duration of response
ECOG = Eastern Cooperative Oncology Group
MTD = maximum tolerated dose
nM = nanomolar
NE = not evaluable
NGS = next-generation sequencing
NSCLC = non–small-cell lung cancer

ORR = objective response rate
OS = overall survival
PD = progressive disease
PFS = progression-free survival
PK = pharmacokinetics
PR = partial response
PS = performance status
QD = once daily
RP2D = recommended Phase 2 dose
SAE = serious adverse event
SD = stable disease
TRAE = treatment-related adverse event
uPR = unconfirmed partial response
VUS = variant of unknown significance