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ACCURACY: A Phase 2 Trial of AL101, a Selective Gamma Secretase Inhibitor, in Subjects With Recurrent/Metastatic (R/M) Adenoid Cystic Carcinoma (ACC) Harboring *NOTCH*-Activating Mutations (*NOTCH*^{mut}): Results of 6-mg Cohort

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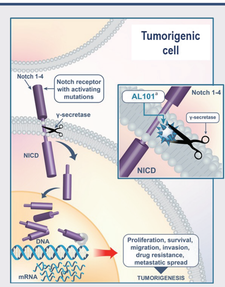
BACKGROUND

- NOTCH signaling pathway dysregulation plays a key role in tumorigenesis in several cancers, including adenoid cystic carcinoma (ACC)[1,2]
- ACC is a rare cancer of the secretory glands, accounting for about 10% of all salivary gland tumors[3,4]
- ACC is an immunologically "cold" tumor that is refractory to chemotherapy, with a high recurrence rate (≈50%) after initial surgery; there is no accepted standard of care or approved therapy for patients with recurrent/metastatic (R/M) ACC[5-7]
- *NOTCH* gene mutations are found in a subset of patients with ACC (≈20%)[2,8]; these patients are characterized by a particularly aggressive disease course, a distinct pattern of metastases, and a poor prognosis[2,9]
- AL101 is an investigational small-molecule γ-secretase inhibitor (GSI) that potently and selectively inhibits NOTCH1/2/3/4[10,11]
  - AL101 blocks the final cleavage step by the γ-secretase required for NOTCH activation, thus inhibiting the expression of *NOTCH* target genes (**Figure 1**)
- AL101 has robust antitumor activity in ACC patient-derived xenograft models with activating *NOTCH1* mutations[12]
- Three phase 1 trials have tested AL101 as monotherapy or in combination regimens in >200 patients with solid/hematologic cancer (unselected patient population)
- In the phase 1 study evaluating advanced/metastatic solid tumors refractory to standard therapies, AL101 was generally well tolerated, with manageable adverse events (AE); and the acceptable doses were either 4- or 6-mg intravenously (IV) once weekly (QW)[13]
- In the results previously presented from this phase 2 monotherapy study (see **Figure 2** below), the results from the 4-mg cohort were a disease control rate (DCR; partial response [PR] + stable disease [SD]) in 29 of 41 patients (71%) according to the updated investigator assessment, including PR in 6 patients (15%), and AL101 at 4 mg QW was well tolerated[14]

Figure 1. NOTCH Signaling and AL101 Mechanism of Action



*AL101 is an investigational new drug in clinical development.
DNA, deoxyribonucleic acid; mRNA, messenger ribonucleic acid; NICD, NOTCH intracellular domain.

METHODS

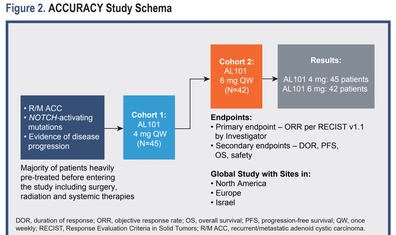
Primary Objective

- To assess the clinical activity of AL101 using radiographic assessments and Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1 in patients with ACC and *NOTCH*-activating mutations

Study Design

- Phase 2, non-comparative, open-label, multicenter study (**Figure 2**)[15]
- Eligible patients received AL101 4-mg IV QW (Cohort 1) or 6-mg IV QW (Cohort 2) until progressive disease (PD), unacceptable toxicity, or withdrawal of consent
- Patients undergo radiographic assessments every 8 weeks during treatment, with an end-of-study visit 30 days after the last treatment and long-term follow-up every 3 months

Figure 2. ACCURACY Study Schema



DOR, duration of response; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; QW, once weekly; RECIST, Response Evaluation Criteria in Solid Tumors; R/M ACC, recurrent/metastatic adenoid cystic carcinoma.

Eligibility Criteria

Key Inclusion Criteria

- Adults (aged ≥18 years) with histologically confirmed R/M ACC with activating *NOTCH1/2/3/4* mutation(s)
- Not amenable to potentially curative surgery or radiotherapy
- Radiographic or clinical progression within 6 months of signing informed consent
- Patients with newly diagnosed metastatic disease are allowed
- Patients with nodal or visceral metastasis must have ≥1 target lesion that is measurable per RECIST version 1.1
- Patients with bone-exclusive disease are eligible if bone lesions are evaluable by computed tomography or magnetic resonance imaging as per modified MD Anderson Bone Response Criteria

Key Exclusion Criteria

- Diagnosis of a malignancy in the past 2 years
- Current or recent (within 2 months of study drug administration) gastrointestinal disorders that increase the risk of diarrhea, such as inflammatory bowel disease
- Evidence of uncontrolled, active infection
- Symptomatic central nervous system metastases
- Completed palliative radiotherapy <7 days before initiating study drug
- Eastern Cooperative Oncology Group performance status ≥2

Statistical Considerations

- A response rate of ≤8% is considered not clinically significant
- The expansion of Cohort 1 to a maximum of 45 patients and Cohort 2 to a maximum of 42 patients will provide ≥80% power in each cohort to test the hypothesis of achieving an increase of the response rate from 8% to 25% using a type I error of 5%

RESULTS

Patients

- All 42 patients enrolled in the AL101 6-mg cohort were treated and evaluable for safety; of these patients, 33 were evaluable for efficacy (**Table 1**)
- Most patients (52%) had received prior systemic cancer therapy in the AL101 6-mg cohort (**Table 1**)
  - Prior chemotherapy was administered to 48% of patients in the AL101 6-mg cohort (**Table 1**)
- Most patients (98%) had undergone prior cancer surgery and/or radiotherapy in the AL101 6-mg cohort (**Table 1**)
- A median of 2 cycles per patient were initiated in the AL101 6-mg cohort, corresponding to a median time of 1.68 months on treatment (**Table 1**)
- The median time on study, defined as time from first dose to last contact, was 7.7, 4.1, 4.9 months for PR, SD, PD, respectively
- The median time on treatment, defined as time from first to last dose, was 7.2, 3.0, 1.5 months for PR, SD, PD, respectively

Table 1. Patient Disposition and Baseline Characteristics

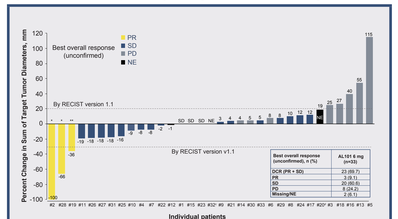
	AL101 6-mg QW (N=42)
Enrolled (signed consent), n (%)	42 (100)
Treated,[a] n (%)	42 (100)
Evaluable for safety[b]	42 (100)
Evaluable for efficacy[c]	33 (78.6)
Not evaluable for efficacy	9 (21.4)[d]
Sex, n (%)	
Male	24 (57.1)
Female	18 (42.9)
Age, median (range), y	59 (25-80)
Race, n (%)	
White	33 (78.6)
Black or African American	2 (4.8)
Asian	1 (2.4)
Other	0
Not reported	6 (14.3)
ECOG PS, n (%)	
0	17 (40.5)
1	25 (59.5)
Prior systemic treatment,[e] n (%)	22 (52.4)
Prior chemotherapy treatment, n (%)	20 (47.6)
Prior radiation therapy, n (%)	41 (97.6)
Prior cancer surgery, n (%)	41 (97.6)
Status at screening,[f] n (%)	
Metastatic disease	35 (83.3)
Locally recurrent disease	12 (28.6)
Treatment-naive and metastatic	6 (14.3)
Most common sites of recurrence or progression,[f] n (%)	
Lung	22 (62.4)
Bone	14 (33.3)
Liver	12 (28.6)
Bone-only disease, n (%)	0
Patients who discontinued AL101,[a] n (%)	35 (83.3)
PD	12 (28.6)
AEs	8 (19.0)
Physician decision	6 (14.3)
Patient decision	5 (11.9)
Death	4 (9.5)
Patients still receiving AL101,[a] n (%)	7 (16.7)[g]
Number of cycles initiated by patient, median (range)	2 (1-10)
Time on study,[h] median (range), months	3.86 (0.4-11.6)
Time on AL101, median (range), months	1.68 (0-8.3)

Data cutoff as of July 9, 2021.
[a]Safety analysis set is used as the denominator.
[b]Safety analysis set includes all patients who receive at least 1 infusion of study drug, including partial infusions.
[c]Efficacy-evaluable analysis set includes all patients who receive at least 1 complete infusion of study drug, have measurable disease at baseline per Response Evaluation Criteria in Solid Tumors version 1.1 or modified MD Anderson Bone Response Criteria for bone-exclusive disease and have at least 1 post-baseline on-study assessment of tumor response.
[d]As of cutoff date, 33 patients were evaluable for efficacy. 6 patients discontinued prior to the first post-baseline radiologic assessment; 3 patients received drug but had not yet reached their first post-line assessment.
[e]Includes adjuvant and neoadjuvant treatment.
[f]Patients may present with more than 1 site of recurrence or progression.
[g]Of these 7 patients, 4 are part of the efficacy population, and 3 are part of the safety population. The 4 patients had their first efficacy evaluation, and 3 patients were receiving drug, but did not reach the first post-baseline assessment.
[h]Defined as time from first dose to last contact.
AE, adverse event; ECOG PS, Eastern Cooperative Oncology Group performance status; PD, progressive disease; QW, once weekly.

Efficacy of AL101 6-mg QW

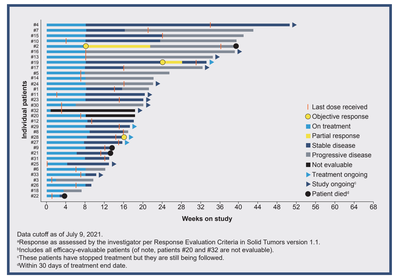
- Among 33 evaluable patients who received AL101 6-mg, the investigator assessment of best response based on RECIST version 1.1 was (**Figures 3-5**):
  - DCR (PR + SD): 23 patients (69.7%)
  - PR: 3 patients (9.1%)
  - SD: 20 patients (60.6%)
  - PD: 8 patients (24.2%)
  - Not evaluable: 2 patients (6.1%)
- The median progression-free survival (PFS) was 3.7 months in the AL101 6-mg cohort
- The median overall survival (OS) was 9.1 months in the AL101 6-mg cohort

Figure 3. Best Overall Responses[a] by Investigator Review in AL101 6-mg Cohort (n=33)[b]



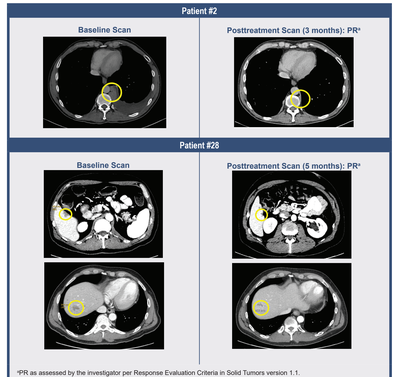
Data cutoff as of July 9, 2021.
[a]Response as assessed by investigator per RECIST version 1.1.
[b]Includes all efficacy-evaluable patients.
[c]Patient #32 has a best overall response of NE because no post baseline measurements were recorded but is included here as zero for completeness.
[d]Patient #20 has a best overall response of NE; the percent change calculation excludes tumors that are measured at screening only (T5).
[e]Confirmed responses.
[f]Unconfirmed response.
DCR, disease control rate; NE, not evaluable; PD, progressive disease; PR, partial response; RECIST, Response Evaluation Criteria in Solid Tumors; SD, stable disease.

Figure 4. Time of Objective Response[a] by Investigator Review in AL101 6-mg Cohort (n=33)[b]



Data cutoff as of July 9, 2021.
[a]Response as assessed by the investigator per Response Evaluation Criteria in Solid Tumors version 1.1.
[b]Includes all efficacy-evaluable patients (of note, patients #20 and #32 are not evaluable).
[c]These patients have stopped treatment but they are still being followed.
[d]Within 30 days of treatment end date.

Figure 5. Radiographic Scans of Two Patients Who Achieved Partial Responses After AL101 6-mg Treatment



[a]PR as assessed by the investigator per Response Evaluation Criteria in Solid Tumors version 1.1.
PR, partial response.

Safety of AL101 6-mg QW

- All 42 treated patients in the AL101 6-mg cohort experienced treatment-emergent AEs (TEAE), which were treatment related in 41 patients (97.6%; **Table 2**)
- Thirty-two patients (76.2%) in the AL101 6-mg cohort had grade 3/4 AEs, which were treatment related in 27 patients (64.3%; **Table 2**)
- Twenty-six patients (61.9%) reported at least 1 serious TEAEs in the AL101 6-mg cohort, 13 (31.0%) of which were considered to be treatment related (**Table 2**)
- There were 4 deaths (9.5%) resulting from TEAEs in the AL101 6-mg cohort (**Table 2**)

Table 2. Safety Summary

	AL101 6-mg (N=42)	
	Treatment emergent, n (%)	Treatment related, n (%)
Any AE	42 (100)	41 (97.6)
Any grade 3/4 AE	32 (76.2)	27 (64.3)
Any SAE	26 (61.9)	13 (31.0)
Any deaths	4 (9.5)	1 (2.4)[a]
AEs leading to discontinuation of AL101	11 (26.2)	NA
AEs requiring dose interruption of AL101	25 (59.5)	NA
AEs requiring dose reduction of AL101	10 (23.8)	NA
AEs requiring dose delays of AL101	2 (2.0)	NA

Data cutoff as of July 9, 2021.
[a]Acute respiratory distress syndrome.
AE, adverse event; NA, not available; SAE serious adverse event.

- Treatment-related diarrhea was common and occurred in 32 (76.2%) patients in the AL101 6-mg cohort (**Table 3**), consistent with reports of NOTCH pathway inhibition[16]
  - Most events were grade 1/2 in 26 (61.9%) patients in the AL101 6-mg cohort
  - Treatment-related serious diarrhea occurred in 4 patients (9.5%) in the AL101 6-mg cohort

Table 3. Treatment-Related AEs Reported in ≥15% of Patients

	AL101 6-mg (N=42)	
	Any grade, n (%)	Grade 3/4, n (%)
Diarrhea	32 (76.2)	6 (14.3)
Fatigue	20 (47.6)	2 (4.8)
Nausea	17 (40.5)	2 (4.8)
Hypophosphatemia	12 (28.6)	1 (2.4)
Vomiting	11 (26.2)	2 (4.8)
Decreased appetite	11 (26.2)	1 (2.4)
Dry mouth	9 (21.4)	0
Rash	9 (21.4)	0
Cough	8 (19.0)	0
Dermatitis acneiform	7 (16.7)	0
Epistaxis	7 (16.7)	0
Rash maculo-papular	6 (14.3)	2 (4.8)

Data cutoff as of July 9, 2021.
AE, adverse event.

Pharmacokinetics

- Pharmacokinetic (PK) parameters for AL101 determined by noncompartmental analysis were similar to PK data from the phase 1 study[13]
  - AUCs following the first dose and fourth dose (steady state) were 1.6 and 1.2 fold higher in the 6-mg compared to the 4-mg cohort (**Table 4**)

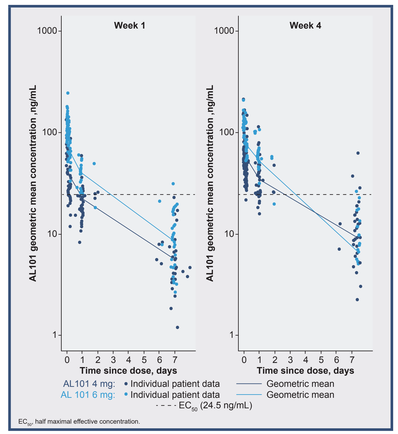
Table 4. Pharmacokinetic Characteristics of AL101 at the First Dose (Week 1) and at Steady State (Week 4)

Cohort	Week	T_{max} (h), median (min, max) [n]	C_{max} (ng/mL) GM (GeoCV%) [n]	$T_{1/2}$ (h) GM (GeoCV%) [n]	$AUC_{(0\text{-}168)}$ (h*ng/mL) GM (GeoCV%) [n]	CL (mL/h) GM (GeoCV%) [n]	AR C_{max} GM (GeoCV%) [n]	AR $AUC_{(0\text{-}168)}$ GM (GeoCV%) [n]
4-mg	1	1.00 (1.00, 2.00) [40]	118 (35.9) [40]	63.7 (35.3) [40]	2840 (44.8) [38]	1140 (49.5) [40]	NA	NA
6-mg	1	1.00 (1.00, 4.00) [21]	180 (25.7) [21]	53.7 (36.2) [20]	4540 (37.8) [20]	1150 (40.7) [20]	NA	NA
4-mg	4	1.00 (1.00, 2.00) [36]	131 (41.6) [36]	60.0 (58.8) [33]	4520 (50.1) [31]	950 (58.3) [34]	1.14 (35.6) [35]	1.56 (33.0) [28]
6-mg	4	1.00 (1.00, 1.00) [16]	182 (16.9) [16]	58.7 (42.5) [13]	5440 (31.4) [13]	1050 (35.4) [14]	1.03 (20.0) [16]	1.34 (26.2) [13]

AR, accumulation ratio (week 4/week 1); $AUC_{(0\text{-}168)}$, area under the concentration–time curve from time 0 to time 168 h; CL, clearance; C_{max}, maximum plasma concentration; GeoCV%, geometric coefficient of variation %; GM, geometric mean; n, number of patients; NA, not applicable; $t_{1/2}$, terminal half-life; T_{max}, time to maximum plasma concentration.

- By week 4, mean plasma concentration of AL101 was extrapolated to be above the half-maximal effective concentration (EC_{50}: 24.5 ng/mL) for 2.6 days in the 4-mg cohort, and 3.3 days at 6-mg (**Figure 6**)
  - EC_{50} was determined using concentration–response modeling of human pharmacodynamic (PD) data from the phase 1 study[13] (**Figure 6**)

Figure 6. AL101 Plasma Concentration Over Time

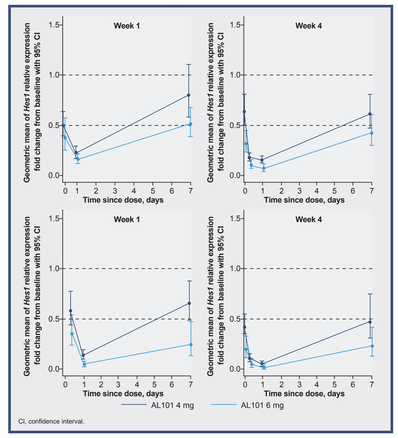


EC_{50}, half maximal effective concentration.

Pharmacodynamics

- Changes in the expression of PD biomarkers (NOTCH-induced *Hes1* and *Hes4* genes) were assessed in peripheral whole blood (PWB) for AL101 4-mg and AL101 6-mg cohorts
  - PWB was collected predose and at 7 hours, 1 day, and 7 days after the first and fourth doses
  - Messenger RNA expression was determined by quantitative real-time polymerase chain reaction
- Reductions in expression of PD biomarkers in PWB observed
  - The mean peak *Hes1* and *Hes4* inhibition (change from baseline) observed after the first dose of AL101 was >75% for both cohorts, with the 6-mg cohort slightly higher (**Figure 7**)
  - At week 4 steady state trough (predose and day 7), *Hes1* and *Hes4* mean inhibition was sustained at about 35% and 55%, respectively for the 4-mg cohort, and higher in the 6-mg cohort at about 60% and 80% (**Figure 7**)

Figure 7. Mean *Hes1* and *Hes4* Change From Baseline Over Time



CI, confidence interval.

SUMMARY AND CONCLUSIONS

- Safety of AL101 6-mg QW
  - AL101 6-mg QW treatment in patients with ACC appeared to be well tolerated with manageable side effects that were similar to those seen in the 4-mg cohort with no new AEs specific to the 6-mg dose. These AEs were all consistent with those noted in trials with GSIs
  - The most common TRAEs of any grade were diarrhea (76%), fatigue (48%), nausea (41%), hypophosphatemia (29%), vomiting (26%), and decreased appetite (26%)
    - Most of these TRAEs were of grade 1/2 severity
  - Serious TRAEs were reported in 31% of patients
  - TEAEs leading to discontinuation were observed in 26% of patients
  - Two patients had a grade 4 TRAE (one with seizure and one with drug-induced liver injury), and 1 patient died resulting from acute respiratory distress syndrome
- Efficacy of AL101 6-mg QW
  - DCR (PR + SD) by investigator assessment was noted in 23 of 33 patients (70%), as compared with 29 of 41 patients (71%) in the AL101 4-mg cohort, including:
    - Best response of PR achieved in 3 of 33 patients (9%), as compared with 6 of 41 patients (15%) in the AL101 4-mg cohort
  - The median PFS was 3.7 months in both 6-mg and 4-mg cohorts
  - The median OS was 9.1 months, as compared with 9.3 months in the AL101 4-mg cohort
- Pharmacokinetics and pharmacodynamics
  - PK data shows mean plasma AL101 concentration AUC in week 1 and at steady state was 1.6 fold and 1.2 fold higher, respectively, in the 6-mg cohort compared to 4-mg
  - NOTCH inhibition (mean *Hes4* inhibition) in PWB was sustained at >50% for AL101 4-mg and >75% for AL101 6-mg at steady state
- The increase in AL101 dose from 4 mg QW to 6 mg QW, while resulting in increased exposure and NOTCH pathway inhibition in peripheral blood mononuclear cells, did not translate into increased efficacy, possibly due to the involvement of other pathways
- The study is ongoing and the results, including additional biomarkers, will be updated when the study is complete

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