1. Postmarketing surveillance Overview

1.1 Re-examination period

25 August 2017 ~ 24 August 2020

1.2 Number of subjects

During the re-examination period, a total of 71 subjects were enrolled but 5 subjects were excluded from analysis as the site Principal Investigator withdrew from PMS; data for these 5 subjects were not used. Therefore, a total of 66 subjects were included in the **Full Analysis Set**. Among these, 61 subjects were included in the **Safety Analysis set**; 1 subject who was administered BELKYRA® Inj. prior to the date of consent, and 4 subjects who did not meet the inclusion/exclusion criteria were excluded. These 5 subjects were treated with Belkyra and were not included in the Safety Analysis set but are still included in the report under Section 3.1.6. Of the 61 subjects, 57 subjects were included in **Effectiveness Analysis Set**; 4 subjects with missing information on effectiveness evaluation were excluded (Table 1).

Table 1. Analysis Set

	No. of Subjects n (%)
Full Analysis Set[1]	**66 (100.00)**
Subjects who were administered BELKYRA® Inj. prior to the date of consent	1 (1.52)
Subjects who did not meet the inclusion/exclusion criteria	4 (6.06)
Safety Analysis Set[2]	**61 (92.42)**
Subjects with missing information of effectiveness evaluation	4 (6.06)
Effectiveness Analysis Set[3]	**57 (86.36)**

No of Subjects (%): (No of Subjects in each category) / (No of Subjects in Full Analysis Set) × 100
[1] Full Analysis Set included all subjects whose case report forms were retrieved
[2] Subjects who received an initial BELKYRA® Inj treatment, completed the (non-treatment) follow-up/exit visit within 3 months of the last BELKYRA® Inj treatment for safety information with case report forms retrieved were included in Safety Analysis Set
[3] Subjects who received an initial BELKYRA® Inj treatment and were evaluated for effectiveness of BELKYRA® Inj for the treatment of submental fullness due to submental fat by the investigator or by the subject were included in Effectiveness Analysis Set
A total 71 subjects were enrolled but 5 subjects were excluded from analysis as site withdrew from PMS; data for these 5 subjects were not used

Number of study institutions	The case report forms (CRFs) for 66 subjects were retrieved from 3 investigators at 3 institutions for the re-examination period from 25 August 2017 to 24 August 2020.
Surveillance method	The study will sequentially enrol eligible Korean subjects treated with BELKYRA® Injection (hereinafter "BELKYRA® Inj.") at each of the selected clinic(s)/hospital(s) from the date of contract until 600 patients have completed the follow-up during the study period. The decision to treat a patient with BELKYRA® Inj. is determined by the investigator and patient prior to the decision to include the patient in the study.

Case report form	[redacted]
Intensive investigation	No events of special interest were identified in the protocol for this study. During the re-examination period, the focus will be on observing and investigating known adverse events (AEs) and unexpected AEs regardless of the causal relationship to this drug and occur very rarely.

1.3 Administration listing of Postmarketing surveillance

Site No.	Region	Site Type	Department	Sites	Investigator	CRF No.	Contracted date	Surveillance Period	No. of cases contracted	No. of cases retrieved
003	Seoul	Clinic	Dermatology	Apgujeong Oracle-Dermatology	[redacted]		2018-09-04	2018-09-11~20-2-02-27	60	47
005	Daejeon	Clinic	Dermatology	Daejeon Oracle-Dermatology			2018-10-22	2019-05-04~2019-09-28	20	5
025	Seoul	Clinic	Plastic surgery	Goldenview Plastic Surgery Clinic			2018-09-05	2019-05-20~2020-03-07	20	14
Total									100	66