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MFDS's Operation of Clinical Trial Authorization and Safety Management

The MFDS publishes 2019 clinical trial authorization status and safety management policy

☐ According to the announcement from the Ministry of Food and Drug Safety (MFDS, Minister Lee Eui-Kyung) and the Korea National Enterprise for Clinical Trials[1] (KoNECT, Chair Byoung-Jun Bae), the joint analysis of 2019 clinical trial authorization landscape showed that the number of authorizations totalled 714 cases, a 5.2% increase compared to that of 2018 (697 cases), and exceeded 700 cases for the first time.

○ As the number of clinical trials is showing a steady growth, the MFDS plans to prioritize the protection of test subjects' safety and rights in the process of strengthening the management, and to improve clinical trial review system in a more efficient and reasonable manner.

<< Clinical Trial Authorization Landscape for Pharmaceuticals >>

☐ Main trends related to the clinical trial in the last year include ▲steady rise in the number clinical trial authorizations ▲burgeoning of phase III clinical trials in Korea ▲growth in the number of clinical trials on diseases affecting the central nervous system, the respiratory system, and the cardiovascular system.

1) National Clinical Trial Support Center consigned by the Ministry of Health and Welfare under Article 18 Paragraph 2 of the "Special Act on Fostering and Support of Pharmaceutical Industry"

① Steady rise in the number clinical trial authorizations

□ The number of clinical trials authorized in 2019 stood at 714, 5.2% increase compared to that of 2018 (679 cases) and 8.5% up compared to that of 2017 (658 cases), showing a steady rise in the past three years.

※ Number of authorized clinical trials: (in 2017) 658 cases → (in 2018) 679 cases → (in 2018) 714 cases

○ On the other hand, the number of newly registered clinical trials around the world amounted to 8,196 in 2019, a decrease by 2.3% compared to that of 2018 (8,386 cases).

- Such an increase in the number of clinical trials in Korea as opposed to the global trend shows that the domestic capacity in clinical trials has been enhanced.

※ Number of clinical trials authorized by the MFDS: (in 2017) 658 cases→(in 2018) 679 cases →(in 2019) 714 cases

※ Number of clinical trials authorized around the world: (in 2017) 7,865 cases→(in 2018) 8,386 cases →(in 2019) 8,196 cases

(Reference: U.S. National Institutes of Health, database of clinical studies (www.clinicaltrials.gov), analyzed by Korea National Enterprise for Clinical Trials)

② Burgeoning of phase III clinical trials in Korea

□ Looking at the number of "clinical trials by pharmaceutical companies" for the development of medicines, the number of phase I clinical trials remained similar to that of 2018. The number of the phase II and phase III clinical trials increased by 10.2% and 10.6%, respectively, compared to those in 2018.

○ Also, the number of authorized "domestic clinical trials," which refer to phase III clinical trials that are conducted only in Korea, stood at 50 in 2019, a 56.3% increase compared to that of 2018.

- Such a growth in the number of "domestic clinical trials" can be considered the result of active development of pharmaceuticals waiting

to apply for approval, and a reflection that domestic capacity in pharmaceutical development has been enhanced.

※ Total number of authorized clinical trials by pharmaceutical companies: (in 2017) 476 cases → (in 2018) 505 cases → (in 2019) 538 cases

※ Number of authorized phase I clinical trials by pharmaceutical companies: (in 2017) 176 cases → (in 2018) 211 cases → (in 2019) 214 cases

※ Number of authorized phase II clinical trials by pharmaceutical companies: (in 2017) 89 cases → (in 2018) 98 cases → (in 2019) 108 cases

※ Number of authorized phase III clinical trials by pharmaceutical companies: (in 2017) 209 cases → (in 2018) 189 cases → (in 2019) 209 cases

※ Number of authorized Phase III "domestic clinical trials" by pharmaceutical companies: (in 2017) 31 cases → (in 2018) 32 cases → (in 2019) 50 cases

Clinical Trial Stage

- (Phase I Clinical Trials) A new medicine is given to humans for the first time and tested for safety and pharmacokinetics, and other criteria
- (Phase II Clinical Trials) After a phase I clinical trial, the new medicine is administered to target patients to experiment on therapeutic effects.
- (Phase III Clinical Trials) Following a phase II clinical trial, a number of patients are treated with the new medicine to confirm safety and therapeutic effect.

③ Clinical trial authorizations by therapeutic function

□ When looking at the clinical trial authorization landscape by the drug's therapeutic function, clinical trial authorizations for cancer treatments accounted for the biggest share with 207 cases followed by those for the endocrine system (69 cases), the digestive system (65 cases), and the cardiovascular system (60 cases).

○ Cancer is one of the most prominent form of severe diseases, and clinical trials as a part of cancer drug development process account for 29%, the highest percentage among all clinical trial authorizations by function for three consecutive years.

※ Percentage of cancer treatment among all clinical trials : (in 2017) 38.1% → (in 2018) 36.4% → (in 2019) 29.0%

- Sorting by the drug's mechanism of action, target therapy constituted the largest share with 112 cases (54.1%), followed by immunotherapy with 55 cases (26.6%).

  * targeted therapy : cancer drugs that interact selectively with a specific molecular targets

  * immunotherapy : cancer drugs that interact selectively with cancer cells by exploiting the immune system.

○ The number of clinical trials on the central nervous system surged by 63.6% to 54 cases in 2019 compared to 33 cases in 2018. Clinical trials are conducted mainly on diseases such as Alzeheimer, depression, stroke.

○ 23 clinical trials were conducted last year on the respiratory system, and 60 trials on the cardiovascular system, which indicate 27.8% (18→23 cases) and 22.4% (49→60 cases) increases, respectively, compared to those of 2018. Main types of respiratory diseases that are currently under clinical trials include asthma, chronic obstructive pulmonary disease, and idiopathic pulmonary fibrosis.

○ 51 clinical trials (7.1%) were conducted on young subjects under 19. By types of targeted effects, clinical trials on medicines affecting the central nervous system accounted for the largest share with 11 cases, followed by clinical trials on drugs for the cardiovascular system (6 cases), the respiratory system (4 cases) and cancer treatment (4 cases). Clinical trials are being conducted on Tourette syndrome, pulmonary arterial hypertension in children, among other diseases.

④ Other Authorization-related Statistics

□ Last year, 476 clinical trials were conducted on generic drugs, showing an increase by 14.7% compared to 415 cases in 2018. The number of clinical trials on biologics decreased by 13.3%, from 233 cases in 2018 to 202 cases in 2019.

○ Among clinical trials on biopharmaceuticals, those on DNA recombinant

proteins amounted to 132 cases, a decrease by 25.4% compared to 177 cases in 2018. On the other hand, the number of clinical trials on biological products increased by 56.5% to 36 cases compared to 23 cases in 2018.

○ Looking at the number of clinical trials by Korean pharmaceutical companies, Chong Kun Dang Pharmaceutical Corp. was ranked first with 23 cases, followed by Daewoong Pharmaceutical Co., Ltd. (17 cases), AddPharma Co. (11 cases), CJ Healthcare (9 cases), and Hanmi Pharm. Co., Ltd. (9 cases).

- Looking at the number of clinical trials by multinational pharmaceutical companies, MSD Korea Ltd. had conducted the highest number of clinical trials (27 cases), followed by Novartis Korea Ltd. (18 cases), Eli Lilly and Company Korea (12 cases), and AstraZeneca Korea Ltd. (12 cases).

- Ranking Contract Research Organizations by the number of clinical trials they conducted, IQVIA Korea was at the top with 34 cases, followed by Covance Korea Services Ltd. (17 cases), and Pharmaceutical Research Associates Korea Ltd. (15 cases).

○ Seoul National University Hospital accounted for the biggest number of clinical trials by researchers, amounting to 27 cases, followed by Asan Medical Center under the under the ASAN Foundation (20 cases), Samsung Medical Center (17 cases), and Yeonsei University College of Medicine's Severance Hospital (13 cases).

<< Promotion of Clinical Trial Safety Management Policy >>

□ The MFDS is moving forward with the “Comprehensive 5-year plan for clinical trial developments” on schedule(Aug. 8, 2019). The plan was established last year to expand treatment opportunities for patients with rare incurable diseases, protect the trial subjects' rights, and enhance capacity in new drug developments.

① Protection of Clinical Trial Subjects' Rights and Enhancement of Safety management

□ As the number of clinical trials in Korea is growing steadily, the MFDS is promoting policies that enhance the safety of test subjects, which would improve the quality of clinical trials.

○ Legal grounds have been established (revised on Dec. 11, 2018) to impose more stringent requirements on the assessment and reporting of safety information on pharmaceuticals used in clinical trials.

- The MFDS is devising a system that allows periodic reporting of all safety information and that can be actively managed and monitored by the government.

※ (as is) Safety information is reported when it is crucial and and related to on matters such as critical and unforeseen side effects

○ With respect to high-risk clinical trials, the Ministry tightened on-site inspections, such as special inspections by product, in addition to the periodic inspections on institutions conducting clinical trials.

※ high-risk clinical trials: Trials in which a number of adverse events have occurred. Participants include preschoolers and other susceptible subjects. Trials on new drugs first developed in Korea and abroad.

- Also, the Ministry will publish the inspection results to ensure transparency and reliability of safety managements.

○ The MFDS also provided guidelines for the preparation of informed consent forms, and compensation agreements and procedures in 2019 to ensure the protection of test subjects' rights.

- In addition, the Ministry is promoting the establishment of a “Central Institutional Review Board” of a public nature and a “Support Center” to be run by the government.

② Resonable Improvement of Clinical Trial Review System

□ The Ministry implemented “preliminary review system” to confirm the integrity of submitted documents in five days to enhance predictability of clinical trials and is operating a “clinical trial review TF” to ensure the efficiency and consistency in the reviews.

○ In order to facilitate clinical trials, the Ministry will replace the status description “approved” with “notified,” when there are changes to clinical trial plans except for matters related to quality.

※ The route of administration, the duration of medication and other matters, on which “notification of changes” are required, will be more thoroughly managed.

○ In the past, only the use of medicines under clinical trials in Korea were allowed in the treatment of patients with rare and incurable diseases for which there is no available medicines in Korea. The Ministry revised the system to also allow the use of medicines under clinical trials abroad.

□ The Ministry said that it will continue to strengthen policies for the improvement of clinical trial quality and the protection of trial subjects’ safety. In addition, the MFDS committed itself to expand treatment opportunities for rare and incurable diseases and enhance national capacity in the development of new drugs.

○ Clinical trial authorization status and the details of clinical trials are made available for everyone at any time via following link on the MFDS website:

https://nedrug.mfds.go.kr > clinical trial information

□ Meanwhile, the MFDS plans to allocate 25.6 billion Korean won budget for 2021 to support the development, commercialization, and swift supply of COVID-19 vaccines, treatments, diagnostic reagents based on its experience in the management of masks and other quarantine items in preparation for the potential prolongation of COVID-19. The Ministry will also ▲reinforce national testing equipment and build new lab facilities for

vaccines and plasma therapy ▲build laboratories to be used exclusively for the quality control and performance testing of in-vitro diagnostic medical devices for infectious diseases, ▲monitor the distribution processes of face masks and other quasi-drugs and inform the public about how to use them appropriately and ▲promote businesses such as the R&D on the approval and review technology for vaccines, treatments and personal protective equipment (e.g. face masks).