<안전성·유효성 심사관련 제출자료목록>

- 비다자100mg 현탁주사용분말, 비엘엔에이치

○ 관련규정 : 의약품등의안전성·유효성심사에관한규정(식품의약품안전청고시 제2007-30호, 2007. 5. 25.) [별표 1] I. 신약, 1. 화학구조 또는 본질조성이 전혀 새로운 신물질 의약품, 제3조제2항제6호 (희귀의약품지정 해제 품목)

구분 \ 제출자료	자료번호																			
	1	3				4[1]								5[1]			6		7	8
		가		나		가	나	다	라	마	바			가	나	다	가	나		
		1)	2)	1)	2)						(1)	(2)	(3)							
자료범위	○	○	○	○	○	○	○	○	○	△	△	△	△	○	○	○	○	○	○	○
제출여부	○	○	○	○	○	×	×	×	×	×	×	×	×	×	×	×	○	×[2]	○	○

면제사유 : 1) 제7조제2항에 따른 제5조제1항제4호 및 제5호의 자료 면제
2) 희귀의약품

○ 제출자료 목록

1. 기원 또는 발견 및 개발경위에 관한 자료

3. 안정성에 관한 자료
   1) 장기보존시험, 가속시험자료
   2) 가혹시험자료

6. 임상시험성적에 관한 자료
   가. 임상시험자료집
   -임상약리
   1) Phase 1 study of 5-Azacytidine (NSC-102816) using 24-hour continuous infusion for 5days (Cancer Chemother Rep 59:1123-1126, 1975)
   2) Phase 1 study of 5-Azacytidine (NSC-102816) (Cancer Chemother Rep 56:413-419, 1972)
   3) Phase 1 study of 5-Azacytidine (NSC-102816) (The Journal of Clinical Pharmacology 16:205-212, 1976)
   4) A Randomized Open Label Two Period Crossover Study to Assess the Bioavailability of Subcutaneous and Intravenous Azacitidine in Subjects with Myelodysplastic Syndromes (MDS) (AZA-2002-BA-002)
   5) The Disposition and Pharmacokinetics in Humans of 5-Azacytidine Administered intracenously as a bolus or by continuous infusion (Cancer research

36;1453-1461, 1976)
6) Absorption, Distribution, and Excretion of 5-Azacytidine (NSC-102816) in Man (Cancer Chemother Rep 56:405-411, 1972)

-치료적탐색/ 치료적확증

7) 5-Azacitidine to induce differentiation in Myelodysplastic syndromes: A Phase 1-2 Pilot study (CALGB 8421)
8) A randomized phase 3 controlled trial of subcutaneous 5-Azacitidine (NSC #102816) vs Observation in myelodysplastic syndromes (CALGB 9221)
9) A comparative clinical trial of 5-azacitidine and guanazole in previously treated adults with acute nonlypmphotic leukemia (Cancer 38:36-41, 1976)
10) Treatment of myelodysplastic syndromes with 5-azacytidine (Leukemia research 26:893-897, 2002)
11) Randomized controlled trial of azacitidine in patients with the myelodysplastic syndromes : A study of the cancer and leukemia group B (Journal of clinical oncology 20:2429-2440, 2002)
12) Impact of azacytidine on the Quality of life of patients with myelodysplastic syndromes treated in a randomized phase III trial : A cancer and leukemia croup B study (Journal of clinical oncology 20:2441-2452, 2002)

7. 외국의 사용현황 등에 관한 자료

- 미국, 스위스 CPP, 스위스 의약품집

8. 국내 유사제품과의 비교검토 및 당해 의약품등의 특성에 관한 자료

- 하이드리아캅셀(히드록시우레아)/한국비엠에스제약